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TITLE: NRH Neuroscience Research Center

PRINCIPAL INVESTIGATOR: Alexander W. Dromerick
Edward Healton, M.D.

CONTRACTING ORGANIZATION: National Rehabilitation Hospital
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14. ABSTRACT

The NRH Neuroscience Research Center (NRC) mission is to promote and accomplish rehabilitation-related basic and applied neuroscience research. AS part of this mission, the NRC: (1) develops new clinical interventions for patients with neurologically based impairments, (2) evaluates the effectiveness of new and existing rehabilitation-related interventions, **(3)** enhances our understanding of the neurophysiological and neuropsychological basis of impairment and disability, and (4) develops new methods to assess human function and performance. In order to be successful with our mission, the NRC is comprised of five research areas. They are as follows: a) High Resolution and Neuromotor Assessment; b) Mechanisms Underlying Recovery from Neurological Illness and Injury; c) Treatment of Neurological Diseases and Injury; d) Pilot Projects; and e) Annual Conference and Expert Panel Projects. Year 4 progress is discussed in detail in this report.

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Introduction:

The NRH Neuroscience Research Center (NRC) grant continues to assist the NRH with the infrastructure to support core elements associated the development of a Neuroscience Research Center. These elements include expansion of staffing; collaborating with other organizations; and developing related projects.

Staffing:

- Sub-investigators- For project A1, Dr Alexander Libin replaced Dr. Tresa Roebuck-Spencer as the Project Coordinator and Drs Chris Kalhorn and Fernando Pagan with Georgetown University Hospital Movment Disorder Center have been added to the study.
- Research Investigator- Koen Putman, PhD, PT of the Free University of Brussels, a principal in the European study, to apply for a European Community Maria Currie Fellowship and for a Fulbright Scholarship. Dr. Putman was successful in acquiring the Fulbright Scholar designation and joined the NRH group in May 2006. Dr. Putman's faculty liaison at the NRH will be Dr. DeJong.
- Appointment of Alexander W. Dromerick, MD as the Director of the NRC and PI for the NRC grant. Please see Addendum for letter from Edward Healton and DAMD17-02-2-0032; Modification P00007 from the grants officer Cheryl Miles.

Collaborating with other organizations:

- National Institutes of Health (NIH)
- Uniformed Services University Health Sciences (USUHS)
- Georgetown University Medical Center/GUH
- National Institute on Disability and Rehabilitation Research (NIDRR)
- The Miami Project
- The Rehabilitation Institute of Chicago (RIC)
- University Maryland
- Children's National Medical Center

Developing related projects:

Currently performing

- NIDRR- Rehabilitation Training Center for Spinal Cord Injury
- NIH-
    - Transcranial Direct Current Stimulation study in individuals with stroke.
    - National Capital Area Rehabilitation Research Networks

Project A1: A Computerized Neuropsychological Battery for Parkinson's Disease: Application for Population Surveillance, Early Detection, and Monitoring Disease Progression

Funding period: Year 4 of 3-year funding period

Status: Collecting data

Principal Investigators: Joseph Bleiberg, PhD
Co-investigators: Alexander Libin, Ph.D. (project coordinator), Justin Carter, M.S., Mark Lin, M.D., Zachary Levine, M.D., Fernando Pagan, M.D., Christopher Calhorn, M.D. and Robert Kane, Ph.D.

Consultants: Dennis Reeves, PH.D., Jose Contreras, Ph.D. and Kathy Winter, M.S.

Abstract:
Parkinson's disease (PD) is a neurodegenerative disorder that presents with a specific set of motor symptoms, including tremor, rigidity and bradykinesia. PD also typically affects cognition and mood similar to that observed in other subcortical neurodegenerative diseases. Approximately 1% of the population over age 50 suffers from PD. Although 40% of patients with PD are between the ages of 50 and 60, there is evidence that "early-onset" PD is on the rise, with an estimated 10% of recently diagnosed patients under age 40. Current therapies for PD focus on amelioration of PD symptoms and slowing disease progression. Future therapies, however, will focus on arresting and even reversing the disease process. Since substantial neuropathologic change, as indicated by greater than 60% loss of dopaminergic neurons, typically precedes manifestation of clinical symptoms in PD, future therapies likely will create a compelling need for early identification in order to permit initiation of treatment prior to the occurrence of extensive CNS insult. The early loss of dopaminergic neurons in PD suggests that subtle neurocognitive changes and subclinical motor symptoms may be seen early in the disorder, possibly before the onset of symptoms necessary for a clinical diagnosis. A test battery sensitive to subtle cognitive dysfunction and subclinical motor symptoms will aid in early detection of PD and monitoring of disease progression. The DoD-developed Automated Neuropsychological Assessment Metrics (ANAM) provides a well-developed starting point. Sensitivity of this measure to cognitive change has been demonstrated in sports concussion, fatigue, exposure to altitude, systemic illness, and pain secondary to headache. The primary objective of the present study is to develop an effective and highly efficient computerized testing system for population surveillance, early identification, and clinical monitoring in PD, using ANAM as the cognitive component. PD symptom specific measures of mood and motor functioning will be developed and added to the current ANAM test battery. Special emphasis will be placed on measures that target the earliest subclinical symptoms of PD that would normally go undetected in the typical neurological exam. Not only will this new ANAM battery be the first of its kind to focus on subtle cognitive change in neurodegenerative disease, it will continue to

be both cost- and time-efficient and able to be universally administered using a simple computer and mouse interface.

Progress and Outcomes:
CURRENT (2006)
ANAM Motor battery development
Since June 2005, ANAM Motor battery tasks and the "shell" from which to run them were completed. After much collaboration and effort, instructions for each task were finalized along with task specifications (e.g., number and duration of trials). Descriptions of the tasks and task components will be included in the final ANAM motor battery and progress on each to date was reported in the 2005 progress update.

Pilot data collection
Pilot data has been collected from 40 subjects. Thirteen of these subjects serve as age, education and gender matched controls. Twenty-seven subjects are diagnosed with Parkinson's disease. Of these 27, 20 subjects were tested one time as part of a cross-sectional design. The remaining seven were tested multiple times as part of a repeated measures design examining patients' change on and off medication as well as before deep brain stimulation surgery (DBS) with subsequent follow up sessions after surgery completion.

Subject recruitment takes place at Washington Hospital Center, the Clinic for Movement Disorders at Georgetown University Hospital, and in several PD support groups in the DC metro area.

LAST YEAR: Primary progress over the last year has been made to finalize the selection and specifications of the primary tasks to be used in the ANAM motor assessment battery. This progress built upon the gains made in the previous years, which included programming a "shell" or common foundation and infrastructure for the motor tasks, developing an overall strategy and architecture for motor task development to maximize compatibility across newly developed tests, and automating transfer of task data from data files to databases. With this framework in place we were able to focus on designing specific motor tasks known from the scientific literature to be sensitive to motor anomalies resulting from damage to the subcortical motor system, as seen with Parkinson's disease.

Progress to data also includes addition of a consultant Dr. Jose Contreras-Vidal, a neuroscientist specializing in the neural networks of motor control from the University of Maryland. Dr. Contreras-Vidal has been instrumental in planning and adapting the above tasks in conjunction with current study investigators.

Barriers and Solutions:
CURRENT (2006): Slow subject retention at Washington Hospital Center demanded other sources for clinical subjects. As a result, the study investigators included colleagues

at Georgetown University Hospital in data collection. While some of the testing conditions have been modified, they are still in accordance with the IRB approved protocol.

LAST YEAR: The primary barrier to clinical validation of the motor measures has been the long duration required for DOD IRB approval. We did not receive final approval until May 2005, approximately 15 months from original submission.

Staffing changes:
Dr. Alexander Libin replaced Dr. Tresa Roebuck-Spencer as the Project Coordinator in September 2005. Justin Carter, M.S., has been formally added as the engineer implementing the new tasks. Collaboration with the Georgetown University Hospital Movement Disorder Center began in February 2006. This site was chosen because of its well reputed relationship with the Parkinson's community. The Center is the first in the DC area to receive a "Center Of Excellence" designation by the National Parkinson Foundation. New investigators at this site include Dr. Chris Kalhorn, a neurosurgeon and Dr. Fernando Pagan, a neurologist.

Plan:
The current plan includes continuing data collection at GUH, WHC, and the broader community, completing a database, creating programs for calculating outcome variables for ANAM Motor tasks, performing statistical analyses and publishing any relevant findings.

The primary task for the current year is two-fold focusing on pilot testing and validation of the new motor measures. The validation techniques combines newly developed motor tasks, existing ANAM cognitive tasks, mood measures and traditional neuropsychological tests, and examines their performance across two groups of subjects such as healthy controls and patients with Parkinson's disease.

LAST YEAR: Motor tasks were programmed and incorporated with mood measures and the existing ANAM software to create a multidimensional computerized testing system.

Publication and Presentations:
n/a

Project B1: **The Impact of Self-Awareness on Functional Outcomes Following Moderate and Severe Traumatic Brain Injury**

Funding period: Year 4 of 3-year funding period

Status: Collecting data

Principal Investigators: William Garmoe
Co-investigators: Anne Newman, Ph.D.

Abstract:
The purpose of the present study is to examine the relationship of self-awareness following traumatic brain injury (TBI) to functional outcome six months after inpatient rehabilitation. It is hypothesized that self-awareness is a salient variable affecting functional outcome. The present study represents one of a series of follow-up studies designed to gain further understanding of self-awareness deficits following brain injury.

Progress and Outcomes:
During the past year data collection has proceeded actively. The research assistant (Dee O'Neill) reviews each admission to the brain injury program for appropriateness for the study. Informal reviews of her screening confirms that she has been approaching all eligible subjects. At the present time approximately 41 subjects have been enrolled and completed Time 1. Approximately 22 subjects have also completed Time 2.

Barriers and Solutions:
The primary barrier at this point is simply the rate of admission of eligible subjects to the NRH Brain Injury inpatient program. Over the past few years a demographic shift has occurred whereby slightly less than 50% of the admissions to the inpatient unit have TBI as a primary diagnosis. However, as noted above, all eligible patients are screened and approached. If a year had not been lost obtaining IRB approval from the Department of Defense, the project currently would be close to having completed enrollment.

Staffing changes:
Dr. Garmoe reduced his time to less than 5% last year. Dee O'Neill recently reduced her time on the grant to 25%. As of May 31, 2006 there was approximately $5250 remaining in the project account. Thus, unless a further source of funding is secured data collection will need to end within the next 1-2 months, or Dr. Garmoe will need to continue to enroll subjects in an unfunded manner. This should leave sufficient funds to complete subjects returning for time two and pay the stipend they receive for participation.

Plan:
Close subject enrollment as of July 31 and focus on retention of subjects returning for Time 2 of the study. At that point focus will shift to data analyses and preparation of papers and conference presentations.

Publication and Presentations:

Garmoe, W., Newman, A., & O'Connell, M. (2005). Self-Awareness early following traumatic brain injury: Comparison of brain injury and orthopedic inpatients using the Functional Self-Assessment Scale (FSAS). Journal of Head Trauma Rehabilitation, 20(4), 348-358.

Project B2: Gait Restoration in Stroke and Incomplete SCI Patients Using the Lokomat Robotic Treadmill System

Funding period: Year 4 of 4-year funding period

Status: Ongoing

Principal Investigators: Joseph Hidler, PhD

Co-investigators: Edward Healton, MD, MPH

Abstract

The primary objectives of this study are two fold. For the stroke leg of the study, our goal is to determine whether robotic-assisted gait training using the Lokomat (Hocoma AG, Volketswil Switzerland) improves walking capabilities to a greater extent than conventional gait training in sub-acute, hemiparetic stroke survivors. Here, 50 individuals will be tested at NRH, randomly assigned to either the Lokomat or conventional group. Each subject will receive 24, 1 hour training sessions over a 10-week period. Outcomes will be measured at weeks 0, 4, 8, and 20, and will include over-ground walking speed, 6-minute walk test (endurance), Ashworth (spasticity) and quality of life measures. We hypothesize that because the Lokomat can deliver more intensive, consistent gait training, overall walking ability and lower extremity motor function will improve more in the robot group than in the conventional trained subjects.

In the SCI portion of the study, our primary objective of this project is to determine whether long-term robotic-assisted locomotor training improves the overall health and quality of life of subjects with complete loss of motor function following spinal cord injury. After lesions to descending spinal pathways that result in a complete loss of motor function, patients often experience spasticity, loss in bone density, and a number of other secondary complications. We believe that intensive locomotor training with the Lokomat robotic gait orthosis (Hocoma, Inc., Zurich Switzerland) will lead to reductions in these negative health complications since this therapy promotes dynamic loading of the bones, increases in circulation, and continuous ranging of joint motion. As a result, we postulate that subjects who train on the device will experience improvements in health status and consequently improvements in quality of life.

Progress and Outcomes:

Both the stroke and spinal cord injury portions of this study now have full IRB approval from both Medstar Research Institute and the Department of Defense. For the stroke leg of the study, 24 subjects have completed the training, 5 are currently enrolled in the study and 2 subjects have dropped out. Both subjects who withdrew from the study elected not to continue due to personal reasons and not due to any negative side effects related to the study. Out of the 24 who have completed the study, 13 have received Lokomat training while the other 11 have received conventional PT. Three of

the current 5 subjects are enrolled in the conventional PT group while the other 2 are in the Lokomat group. None of our subjects have experienced any negative effects of being in the study.

For the SCI leg of this study, we have completed the training on 1 individual with SCI and have currently completed session 50 out of 72 in our second individual. We have identified our next trainee who will start training upon the completion of subject #2. Neither of our first two subjects have experienced any negative effects from the study but instead have reported positive improvements in their overall health.

Barriers and Solutions:

None

Staffing changes:

The overall budget remained unchanged.

PLAN

For both the stroke and SCI legs of the study, we plan to continue training until reaching our target numbers. For the stroke study, we plan to train 50 subjects and for the SCI study, we will train 5 individuals. We fully expect reaching these targets within the upcoming year.

Publication and Presentations:

A number of presentations and publications have resulted from pilot work done over the past funding cycle that was affiliated with this study:

Publications

J. Hidler, M Carroll, and E. Federovich, "Strength and coordination in the paretic leg of individuals following acute stroke" In Review.

M. Pelliccio, N. Neckel, D. Nichols, and J. Hidler, "Lower limb strength and coordination patterns of chronic stroke subjects in a functional posture", APTA 2006 Combined Sections Meeting, January 2006.

D. Nichols, i. Black, M. Pelliccio, and J. Hidler, "The effects of speed and level of voluntary muscle activation on reflex responses in chronic stroke patients", APTA 2006 Combined Sections Meeting, January 2006.

N. Neckel, D. Nichols, M. Pelliccio, and J. Hidler, "Lower Limb Joint Torque Patterns of Chronic Stroke Subjects in a Standing Position." Society for Neuroscience Annual Meeting, 2005.

i. Black, D. Nichols, M. Pelliccio, and J. Hidler, "The effects of speed and muscle pre-activation on spastic reflex responses in chronic stroke survivors." Society for Neuroscience Annual Meeting, 2005.

Invited Presentations

"Rehabilitation Robotics: Contemporary Issues Surrounding 21st Century Neurorehabilitation", Pinnacle Health Neurology & Rehabilitation Conference, Harrisburg, PA, April 2006 (KEYNOTE SPEAKER).

"Assessment of Walking Ability after Spinal Cord Injury: Tools from Robotics and Engineering", Miami Project to Cure Paralysis Seminar Series, Miami, FL, March 2006.

"Robotic Assessment of Walking Ability in Individuals with SCI", Italian Neurorehabilitation Conference on Treadmill Training, Parma Italy, January 2006.

"Advances in the understanding and treatment of lower limb motor impairments following stroke" Penn State, State College, PA, 2005.
"Robotic devices in the neurorehabilitation of stroke and spinal cord injury", Penn State Colloquia Seminar Series, State College, PA, 2005.

"Introduction: An overview of robotic technologies", American Congress on Rehabilitation Medicine, Chicago, IL, 2005.

Trainees affiliated with the project

Undergraduate Students – Catholic University

Cathryn Jensen
Megan Payne
John Ivanoff
Samantha Muro

Graduate Students – Catholic University

iian Black
Nathan Neckel

Project C1: Stroke Performance Recovery and Outcomes Study

Funding period: 4th year of 4-year funding period

Status: Complete except for September 2006 working conference

Principal Investigators: Brendan Conroy, MD
Co-investigators: Gerben DeJong, PhD, FACRM; Susan Horn, PhD

Sub-contracts/consultants: Institute for Clinical Outcomes Studies (ICOR), Salt Lake City, UT

Abstract:

Stroke Performance Recovery and Outcomes Study examines specific patient characteristics and rehabilitation interventions and their relationship to outcomes. All together, six inpatient rehabilitation facilities in the U.S. and one in New Zealand contributed detailed patient-level data on 1,383 patients--approximately 200 consecutively admitted stroke patients from each site. The study entailed the development of a detailed taxonomy of interventions, the creation of extensive in-depth data collection protocols, the creation of a study database, data analyses, publications, presentations, and project spin-offs to exploit the database. The study is made possible by a cohesive leadership team, the commitment by participating clinical sites, and a number of volunteer investigators who have joined the study as it became better known throughout the country and abroad.

Progress and Outcomes:

1. Continued to analyze the very large database created by the study. The findings have found their way into the manuscripts cited below with additional publications pending.

2. Published***24 manuscripts*** in various health science journals based on the study. See list of publications. These include the preparation of 12 manuscripts for a special supplement of the *Archives of Physical Medicine & Rehabilitation*, the field's most widely cited publication, that appeared in December 2005. Drs. DeJong, Horn, Conroy, and Gassaway were the editors for the supplement.

3. Assembled a team to organize a 1½-day conference to be held in September 2006 based on the study, its methods, and findings. A copy of the conference agenda can be found in the appendix to this report. (See project E1 for detail)

4. Developed plans to merge the study database (N=1,291) with a similar study database (N=532) assembled from 5 rehabilitation centers in 4 European countries.

5. Assisted Koen Putman, PhD, PT of the Free University of Brussels, a principal in the European study, to apply for a European Community Maria Currie Fellowship and for a Fulbright Scholarship. Dr. Putman was successful in acquiring the Fulbright Scholar designation and joined the NRH group in May 2006. Dr. Putman's faculty liaison at the NRH will be Dr. DeJong.

6. Obtained funding to conduct secondary analyses of study data. Specifically, obtained a field-initiated research grant from the National Institute on Disability & Rehabilitation Research (NIDRR) to examine black-white disparities in stroke rehabilitation.

7. Commenced analyses of the nursing intervention data to understand better the contribution of nursing interventions to stroke rehabilitation outcomes.

8. Fostered the development of proposals for similar rehabilitation studies related to joint replacement (funded and underway), traumatic brain injury (to be resubmitted to NIH), and spinal cord injury (submitted to NIDRR).

Barriers and Solutions:

There were no unusual or insurmountable barriers. This past year, we had three main challenges:

1. The study's nursing intervention data were not as complete as the therapy intervention data (e.g., PT, OT, SLP). We have had to make some compromises in the data analyses with respect to nursing. We have found the collection of nursing intervention data to be a problem in similar studies mainly because of nursing shortages, extensive use of agency nurses, and the compliance of weekend nurses.

2. The overall task of assembling a unified and coherent supplement for the *Archives* proved to be more arduous than expected but was successful in the end. The *Archives* supplement has stimulated significant interest in both study's methods and findings.

Staffing changes: None

Plan:

1. Host an international invitational conference in September 2006 based on the results of the study using the special issue of the *Archives* as the basis for conference content.

2. Promote secondary uses of the *Archives of Physical Medicine & Rehabilitation* supplement that incorporates the principal findings from the study.

3. Host Fulbright Scholar from Free University of Brussels who will combine and analyze data from both the American (project database) and European databases. The combined database will include data on over 1,500 stroke patients from the U.S. New Zealand, Germany, Belgium, Switzerland, and the United Kingdom. See No. 5 above.

4. Continue to submit papers to other journals and conferences as opportunities arise and as papers are accepted. Target conferences include the annual meetings of the:

   - American Congress of Rehabilitation Medicine (ACRM)
   - American Society for Neurorehabilitation (ASNR)
   - American Academy of Physical Medicine & Rehabilitation (AAPM&R)
   - International Stroke Association (ISA)
   - American Physical Therapy Association (APTA)
   - American Occupational Therapy Association (AOTA)
   - American Speech & Hearing Association (ASHA)

Publications:

1. Deutsche, Ann, Carl V Granger, Roger C Fiedler, Gerben DeJong, Robert L Kane, Kenneth J Ottenbacher, Allen W Heinemann, John P Naughton, Maurizio Trevisan (2005) "Outcomes and Reimbursement of Inpatient Rehabilitation Facilities and Subacute Rehabilitation Programs for Medicare Beneficiaries with Hip Fracture." *Medical Care.* 43 (September) No. 9, 892-901.

2. DeJong, Gerben and Susan Horn (2005). "Randomized Controlled Trials in Rehabilitation Research." *New Zealand Journal of Disability Studies.* Vol. 11: 120-124.

3. DeJong, Gerben (2005). "Medicare Reform and the American Devolution." *Topics in Stroke Rehabilitation,* 12 (2): 4–14.

4. Zorowitz, Richard D, Smout, Randall J, Gassaway, Julie A, Horn, Susan D (2005). "Prophylaxis for and Treatment of Deep Venous Thrombosis After Stroke: The Post-Stroke Rehabilitation Outcomes Project (PSROP)." *Topics in Stroke Rehabilitation* 12 (Fall), No. 4, 1-10.

5. Zorowitz, Richard D, Smout, Randall J, Gassaway, Julie A, Horn, Susan D (2005). "Antiplatelet and Anticoagulant Medication Usage During Stroke Rehabilitation: The Post-Stroke Rehabilitation Outcomes Project (PSROP)." *Topics in Stroke Rehabilitation* 12 (Fall), No. 4, 11-19.

6. Zorowitz, Richard D, Smout, Randall J, Gassaway, Julie A, Horn, Susan D (2005). "Antihypertensive Medication Usage During Stroke Rehabilitation:

The Post-Stroke Rehabilitation Outcomes Project (PSROP)." *Topics in Stroke Rehabilitation* 12 (Fall), No. 4, 20-27.

7. Zorowitz, Richard D, Smout, Randall J, Gassaway, Julie A, Horn, Susan D (2005). "Neurostimulant Medication Usage During Stroke Rehabilitation: The Post-Stroke Rehabilitation Outcomes Project (PSROP)." *Topics in Stroke Rehabilitation* 12 (Fall), No. 4, 28-36.

8. Zorowitz, Richard D, Smout, Randall J, Gassaway, Julie A, Horn, Susan D (2005). "Neurostimulant Medication Usage During Stroke Rehabilitation: The Post-Stroke Rehabilitation Outcomes Project (PSROP)." *Topics in Stroke Rehabilitation* 12 (Fall), No. 4, 28-36.

9. Zorowitz, Richard D, Smout, Randall J, Gassaway, Julie A, Horn, Susan D (2005). "Usage of Pain Medications During Stroke Rehabilitation: The Post-Stroke Rehabilitation Outcomes Project (PSROP)." *Topics in Stroke Rehabilitation* 12 (Fall), No. 4, 37-49.

10. Guest editors. The study's PI and co-PIs were the guest editors of a special supplement to the *Archives of Physical Medicine & Rehabilitation,* December 2005 for 12 articles based on the findings of the Post-stroke Rehabilitation Outcomes Project (PSROP). NRH investigators also authored the following articles in the supplement.

11. DeJong, Gerben, Susan D Horn, Brendan Conroy, Diane Nichols, Edward Healton (2005). "Opening the Black Box of Post-stroke Rehabilitation: Stroke Rehabilitation Patients, Processes, and Outcomes." *Archives of Physical Medicine & Rehabilitation.* 86(December), No. 12, Suppl 2, 1-7.

12. Horn, Susan D, Gerben DeJong, David Ryser, Peter Veazie, Jeffrey Teraoka (2005). "Another Look at Observational Studies in Rehabilitation Research: Going Beyond the Holy Grail of the Randomized Controlled Trial." *Archives of Physical Medicine & Rehabilitation* 86(December), No. 12, Suppl 2, 8-15.

13. Gassaway J, Horn SD, DeJong G, Smout R, Clark C, James R (2005). "Applying the CPI Approach to Stroke Rehabilitation: Methods and Baseline Results." *Archives of Physical Medicine & Rehabilitation* 86(December), No. 12, Suppl 2, 16-33.

14. Maulden, Sarah, Julie Gassaway, Susan D Horn, Randy Smout, Gerben DeJong (2005). "Timing of Initiation of Rehabilitation After Stroke." *Archives of Physical Medicine & Rehabilitation* 86(December), No. 12, Suppl 2, 34-40.

15. Latham N, Jette D, Slavin M, Richards L, Smout R, Horn S. Physical Therapy During Stroke Rehabilitation for People with Different Walking Abilities.

Archives of Physical Medicine & Rehabilitation. 86(December), No. 12, Suppl 2, 41-50.

16. Richards, Laurie, Nancy Latham, Diane Jette, Laura Rosenberg, Randy Smout R, Gerben DeJong (2005). "Characterizing Occupational Therapy Practice in Stroke Rehabilitation." *Archives of Physical Medicine & Rehabilitation* 86(December), No. 12, Suppl 2, 51-60.

17. Hatfield B, Millet D, Coles J, Gassaway J, Conroy B, Smout R. Characterizing Speech and Language Therapy in Stroke Rehabilitation (2005). *Archives of Physical Medicine & Rehabilitation* 86(December), No. 12, Suppl 2, 61-72.

18. Conroy B, Zorowitz R, Horn S, Ryser D, Teraoka J, Smout R (2005). "An Exploration of Central Nervous System Medication Use and Outcomes in Stroke Rehabilitation." *Archives of Physical Medicine & Rehabilitation.* 86(December), No. 12, Suppl 2, 73-81.

19. James R, Gines D, Horn SD, Gassaway J, Smout R (2005). Nutrition as a Rehabilitation Intervention. *Archives of Physical Medicine & Rehabilitation* 86(December), No. 12, Suppl 2, 82-92.

20. DeJong, Gerben, Susan D Horn, Randy Smout, David Ryser (2005). "The Early Effects of the Inpatient Rehabilitation Facility Prospective Payment System on Stroke Rehabilitation Case-mix, Practice Patterns, and Outcomes." *Archives of Physical Medicine & Rehabilitation* 86(December), No. 12, Suppl 2, 93-100.

21. Horn, Susan D, Gerben DeJong, Randy Smout R, Julie Gassaway, Roberta James, Brendan Conroy (2005). "Stroke Rehabilitation Patients, Practice, and Outcomes: Is Earlier and More Aggressive Better?" *Archives of Physical Medicine & Rehabilitation* 86 (December), No. 12, Suppl 101-114.

22. McNaughton Harry, Gerben DeJong, Randy Smout, John Melvin, Murray A Brandstater (2005). "A Comparison of Stroke Rehabilitation Practice and Outcomes Between New Zealand and United States Facilities." *Archives of Physical Medicine & Rehabilitation* 86(December), No. 12, Suppl 2, 115-120.

Presentations

DeJong, G. "The Post-stroke Rehabilitation Outcomes Project." A presentation made to the International Stroke Rehabilitation Congress sponsored by CERISE ["Collaborative Evaluation of Rehabilitation in Stroke across Europe"] hosted by the Catholic University at Leuven. Leuven, Belgium. February 11, 2006.

Project D1: **Determining the Psychometric Properties of the NRH Pragmatic Communication Skills Rating Scale**

Funding period: Year 3 of 1-year funding period

Status: Ongoing

Principal Investigators: Christine Baron
Co-investigators: Melissa Richman, Pei-Shu Ho, Ph.D.

Sub-contracts/consultants:

- n/a/

Abstract:
Speech-language pathologists (SLPs) complete the NRH Pragmatic Communication Skills Clinician Rating Scale as part of their evaluation of right-hemisphere stroke survivors. Family members or significant others are asked to fill out the version of the same scale that has been designed for their use. Both of these rating scales have been used clinically without benefit of reliability or validity testing. Reviews of work done with this scale to date have been extremely encouraging, with the caveat that the psychometric properties of the Scale need to be examined. The objective of this project is to determine the reliability and validity of the clinician scale in order to contribute to the profession, current clinical practice and the ability to conduct applied research regarding pragmatic communication changes after stroke in a multi-cultural population.

Progress and Outcomes:
Data collection began April 26, 2004. Data for 27/50 subjects has been collected. Data is currently undergoing analysis.

Barriers and Solutions:
Data collection was halted in December 2005 by the inadequate staffing of the SLP Service and the need for both SLP researchers to provide direct patient care to the exclusion of non-revenue-generating activities.

Staffing changes:
None

Plan:
Currently unfunded. Data is currently undergoing analysis and it is hoped that results will be available July 2006. Results will be submitted to the Clinical Aphasiology Conference, and if accepted, presented at the conference in May 2007.

Publication and Presentations:
Prior research in this area and the current research design and rationale were published as follows:

Baron, C., Hatfield, B. and Georgeadis, A. (2005). Management of communication disorders using family member input, group treatment and telerehabilitation. Topics in Stroke Rehabilitation, 12(2), 47-54.

Project D2: Metabolic Studies in Individuals with Chronic Spinal Cord Injury: The Effects of an Oral Anabolic Steroid and Conjugated Linoleic Acid

Funding period: Year 3 of 2-year funding period

Status: Ongoing

Principal Investigators: Lauro Halstead, MD MPH
Co-investigators: Suzanne Groah, MD, MSPH, Larry Hamm, PhD

Sub-contracts/consultants:

- None

Abstract:
This is a study to investigate the effects of 2 agents—oxandrolone and conjugated linoleic acid (CLA)--in individuals with chronic spinal cord injury (SCI). Oxandrolone is an oral anabolic steroid that has been shown to increase lean body mass and improve pulmonary function. CLA (brand name Tonalin) is a group of polyunsaturated fatty acids found in animal meat, dairy products and other natural sources and has been shown to decrease body fat mass. The purpose of this project is to determine whether oxandrolone, CLA, or both improve body composition and pulmonary function in individuals with T4-C4 ASIA A or B of at least 1 year duration. Subjects will be randomized to 1 of 3 groups: oxandrolone (Group A, n=15), CLA (Group B, n=15), or control (Group C, n=15) groups. All 45 participants will receive baseline liver function tests (LFTs), lipid panel, pulmonary function testing (PFTs) and dual x-ray absorptiometry (DEXA) for body composition analysis. Subjects will then receive either 8 weeks of oxandrolone, 12 weeks of CLA, or neither. Participants will have laboratory studies including lipid panel, LFTs, PFTs, and DEXA during and immediately after the intervention period and 3 months later to determine if any changes are maintained.

Progress and Outcomes:
After a prolonged delay to obtain IRB permission from MRI and DoD, we began screening subjects in April, 2006 and randomized the first subject to Group B later that same month. As of June 22, 2006, we will have screened a total of 9 subjects.
The disposition of these 9 subjects is as follows:

1 was randomized to Group A and is awaiting arrival of the oxandrolone which is due this week;
3 were assigned to Group B; of these, 1 had to withdraw due to unreliable transportation;
2 were randomized to Group C; of these, 1 withdrew so he could continue taking CLA
2 were screened but then unable to participate; and
1 subject is awaiting randomization

Of the 2 subjects in Group B currently taking CLA, 1 had a temporary, possible adverse reaction to the medication. After beginning to take the CLA granola bars, he reported bloating and diarrhea for several days. He elected to remain on the granola bars and the

symptoms subsided spontaneously. Other than this incident, the granola bars have been well tolerated.
During the past year, there was one change to the protocol. At the request of Cognis, the manufacturer of CLA, we have added several additional blood studies obtained at baseline, 12 and 20 weeks for subjects on CLA and half of the control subjects. These studies include: hsCRP, Insulin, Glucose, and Leptin.

Barriers and Solutions:
There have been several barriers that have slowed the progress of this study. The major ones include the following:
1) IRB approval. There was a one year delay in obtaining approval from the IRBs of the DoD and MRI;
2) Medication supply. There was a significant delay in obtaining a supply of the study drug, oxandrolone, from Savient Pharmaceuticals for Group A. As a result, at least one subject lost interest in the study and dropped out. The other subject assigned to Group A is on hold until the medication arrives.
Solution: It is anticipated that oxandrolone will be shipped and arrive at NRH this week.
3) Recruiting subjects. Subjects with C-4 to C-8 ASIA A & B are limited in number and there is competition for their participation from other studies. In addition, it is a group that frequently has unreliable transportatiton.
Solution: Expand inclusion criteria to include SCI Level to T 4; Find funding to assist with transportation.
4) Randomization. Some subjects are dissatisfied with being randomized. For example, one subject assigned to the Control Group did not choose to partcipate as he wanted to continue taking CLA.
Solution: Clarify further at time of screening the rationale for randomization.
5) Availability of DEXA. The DEXA machine is located across the street in the WHC which makes it not easliy accessible and requires approximately 1 hour of 2 staffs' time.
Solution: Continue to pursue acquiring DEXA at NRH.

Staffing changes:
None.

Plan:
Consider additional ways to increase recruitment; explore ways to improve access to reliable transportation; consider expanding the Inclusion criteria to include subjects with T-4 ASIA A and B.

Publication and Presentations:
None.

Project D3: Development and Clinical Validation of a Children's Version of the Automated Neuropsychological Assessment Metrics (ANAM)

Funding period: Year 2 of 1-year funding period

Status: Collecting data

Principal Investigators: Tresa Roebuck-Spencer, PhD

Co-investigators: Joseph Bleiberg, Ph.D. (NRH); Gerard Gioia, Ph.D. (Children's National Medical Center - CNMC); Laura Kenealy, Ph.D. (CNMC)

Sub-contracts/consultants:

- Investigators at CNMC will be paid via a subcontract to CNMC

Abstract:
Every day children experience illnesses, injuries, or take medicines that may change their ability to think quickly and remember things. This study will adapt and validate a group of computerized tests, called the Automated Neuropsychologic Assessment Metrics (ANAM), in order to inform doctors and other health care providers when a child had a change in his or her cognitive functioning. The ANAM battery was originally developed by the US Army to measure changes in thinking abilities in adults. While ANAM has been used with young adults and adolescents in high school, it has not been used with children younger than 13 and a comparable measure in this age group does not exist.

The current study includes three stages. The first stage includes development and pilot testing of a pediatric version of ANAM (ped-ANAM) with children between the ages of 10-12, to demonstrate that children at this age can understand and complete the test. During the second stage, a group of middle school children (between the ages of 10-12) will take ped-ANAM. This phase of the study will establish expected levels of performance in normally developing children and will test for differences in performance between boys and girls and across the three age ranges. In the last stage of this project, sensitivity of ped-ANAM to detect cognitive change in two pediatric clinical groups will be examined using a series of single subject studies. First, children with a diagnosis of ADHD will be tested with ped-ANAM prior to and after receiving medication in order to determine if performance on ped-ANAM changes after receiving medication. Second, children with recent (< 24 hours) history of concussion or mild traumatic brain injury will be tested with ped-ANAM multiple times over several days to 1) demonstrate its use within an emergency medical setting and 2) document its ability to track recovery of cognitive functioning. Data collected from this study will provide evidence of ped-ANAM's use with normal and clinical samples of children and document its sensitivity to cognitive change in children.

Progress and Outcomes:

Final IRB approval from DoD was received in the fall of 2005. As you know development of ped-ANAM was completed last year and regular meetings were held between NRH and CNMC throughout the time we were awaiting final IRB approvals. We have also completed detailed relational databases in Microsoft Access for data storage and later analysis. Phase One of the study was initiated after receiving final IRB approval. We began recruitment through local school districts and community contacts (e.g., postings to various parent and school internet listserves, posting flyers with community groups, and posting flyers within CNMC and local pediatrician offices). We also included information about the study and recruitment contacts in the NRH Research Update and CNMC quarterly "Bear Essentials" newsletter to parents. These recruitment ventures have been quite sucessful. To date we have enrolled and tested 31 subjects with approximately similar numbers of males and females and a good representation of the three age groups. We have also been able to sucessfully recruit children from representative proportions of various ethnic groups. We recently completed continuing review applications with both the Medstar and CNMC IRBs and have received approval to continue to the study for another year.

Barriers and Solutions:
No significant barriers have been encountered. However, recruitment has slowed in the last month due to the fact that children are out of school for the summer. We are broadening our recruitment efforts to include more community groups that work with children during the summer months and plan to run a follow-up ad for recruitment through the CNMC "Bear Essentials" newsletter. We anticipate that recruitment will increase again when the school year starts allowing us to reach our anticipated target number of subjects by the end of the calendar year.

Staffing changes:
none

Plan:
Data collection will continue and recruitment efforts will be increased and modified as described above. Preliminary data analyses will be conducted once we reach half of our target sample to ensure that we are getting appropriate representation of gender, age groups, and ethnicity groups. If necessary targeted recruitment will be initiated to ensure that we include appropriate numbers of children in these groups. At the completion of data collection, statistical analysis will begin with plans to present these analyses at a national conference to be followed by manuscript preparation and submission to a peer-reviewed journal.

Publication and Presentations:
Preliminary presentation of data collected was presented to the ANAM Sports Concussion Working Group conference hosted by Dr. Joseph Bleiberg at NRH between June 9, 2006 and June 10, 2006.

Project D4: **Does constraint induced movement therapy improve upper extremity motor function in individuals following stroke**

Funding period: Year 1 of 1-year funding period

Status: Waiting IRB Approval

Principal Investigators: Alexander Dromerick

Co-investigators: Lori Grimes, OT

Abstract:
This will be an unblinded case series of individuals undergoing Constraint-Induced Movement Therapy (CIMT) at least one year after the onset of the index stroke. The control will be the subject's pre-treatment baseline. There are no medications, procedures, imaging studies, or placebos in this study design. Except for the study treatment, the participants will receive the care prescribed by their physicians or other health care providers.

Participation in the project would involve coming to NRH 5 days a week for a little over two weeks. The participant would receive 3 hours per day of the treatment from a therapist, and s/he would spend this time with the therapist doing intense practice of everyday tasks like buttoning, opening bottles, etc. The participant would be asked to wear a padded mitten on their unaffected hand at home during the two week period, and this would encourage use your affected arm. There would be a half day of testing their arm strength, sensation, thinking, and vision before and after the treatment. The participant would also return 3 months later for another half day of testing.

Progress and Outcomes:
Therapists have been trained to perform treatment intervention and assessment.

Barriers and Solutions:
The project is awaiting approval from Army IRB and will start once we receive final approval

Staffing changes:
None

Plan:
Enroll first patients in August once receive army IRB approval

Publication and Presentations:
N/A

Project E1: Annual Joint NRH/NIH/ACRM/AAMPM&R/NIDRR Conference

Funding period: Year 4 of 4-year funding period

Status: Postponed until January 2006

Principal Investigators: N/A

Abstract:
The purpose of this conference is to discuss the leading opportunities in neuro-rehabilitation, emerging practices in multi-center trials, and best practices research administration. It is cosponsored with several other organizations and will produce an annual report that summarizes the meeting.

Progress and Outcomes:
The conference for year 4 was postponed in order to more appropriately utilize resources.

Barriers and Solutions:
We had to delay the proposed stroke conference because of insufficient funding. We were later able to obtain additional funds and rescheduled the conference from January 2006 to September 2006

Plan:
Host a national invitational conference in September 2006 based on the results of the study using the manuscripts for the special issue of the *Archives* as the basis for conference content. Please see below for details.

Working Conference Based on Findings from CVA Study

A Working Conference

Rethinking Stroke Rehabilitation Practice: Is Earlier and More Aggressive Therapy Better?

Findings from the Post-stroke Rehabilitation Outcomes Project

Agenda
Version 7
(subject to slight modification)

September 8-9, 2006
1½-day meeting
National Rehabilitation Hospital
Washington, DC

DAY 1

07:30 Registration & Breakfast

08:30 Welcoming Remarks[1]

Edward Healton, MD, MPH
National Rehabilitation Hospital
Washington, DC

08:45 Introduction: Purpose & Scope of PSROP and Meeting Expectations

Gerben DeJong, PhD
National Rehabilitation Hospital
Washington, DC

09:05 Going Beyond the Holy Grail of the RCT

Susan Horn, PhD
Institute for Clinical Outcomes Research
Salt Lake City, UT

09:45 Break

[1] The meeting will be recorded and edited for web viewing. This will also assist us in developing a report that will include recommendations for practice and future research.

10:00 PSROP Taxonomy, Methods, & Baseline Results

Julie Gassaway, MPH
Institute for Clinical Outcomes Research
Annapolis, MD

10:40 Commentary & Group Discussion

Alex Dromerick, MD[2]
National Rehabilitation Hospital
Washington, DC

11:10 The Leap-frog Hypothesis: Is Early & More Aggressive Therapy Better?

Susan Horn, PhD
Institute for Clinical Outcomes Research
Salt Lake City, UT

Brendan Conroy, MD
National Rehabilitation Hospital
Washington, DC

12:00 Lunch

Remarks by Ruth Brannon, MA, MSPH, NIDRR project officer
Remarks by Mary Lopez, PhD, OTR, DOD project officer

13:00 Commentary (panel) & Group Discussion

Elliot Roth, MD
Rehabilitation Institute of Chicago
Chicago, IL

Hilary Siebens, MD
UC Irvine
Irvine, CA

Chris McDonnell
CARF
Washington, DC

Dale Strasser, MD
Emory University
Atlanta, GA

[2] Dr. Dromerick will begin with a 5-10 min commentary before the discussion is opened to the floor.

John Melvin, MD
Thomas Jefferson University
Philadelphia, PA

Patrick Murray, MD
MetroHealth
Cleveland, OH

13:45 Workgroup organization and instructions

Instructions to the workgroups, Gerben DeJong, PhD

14:00 Workgroups

14:10 Presentations by authors (about 14 min each)
15:00 Break
15:20 Designated discussants (2-3 discussants/workgroup)
15:50 Workgroup discussion
16:30 Workgroup consensus discussion
16:50 Adjourn

Topics covered by each workgroup:

- Practice patterns and variation across sites
- Is earlier and more aggressive better?
- Recommendations for practice, policy, and research
- Recommendation for stroke rehabilitation quality and accreditation standards
- What are the next steps?

Workgroup A—Therapy Activities

Convener/moderator/facilitator:

Cathy Ellis, PT
National Rehabilitation Hospital
Washington, DC

Recorder:

Julie Gassaway, MPH
ISIS-ICOR
Annapolis, MD

Possible discussants:

Diane Nichols, RPT

National Rehabilitation Hospital
Washington, DC

Deborah Millet, MS, CCC-SLP
LDS Hospital
Salt Lake City, UT

Lauren Rosenberg, OTR
National Rehabilitation Hospital
Washington, DC

Physical Therapy
Nancy Latham, PhD
Boston University
Boston, MA

Occupational Therapy
Lorie Richards, PhD
University of Florida
Gainesville, FL

Speech & Language Therapy
Brooke Hatfield, MS, CCC-SLP
National Rehabilitation Hospital
Washington, DC

Workgroup B—Timing, Medications, Nutrition

Moderator/convener/facilitator:

Richard Zorowitz, MD
University of Pennsylvania
Philadelphia, PA

Recorder:

David Ryser, MD
LDS Hospital
Salt Lake City, UT

Discussants:

Lee Ann Simms, RN
Legacy Health Systems
Portland, OR

Jeffrey Teraoka, MD
Stanford University Hospital
Palo Alto, CA

Timing of Rehabilitation after Stroke
Sarah Maulden, MD, MS
Department of Veterans Affairs
Salt Lake City, UT

Neurotropic Medications
Brendan Conroy, MD
National Rehabilitation Hospital
Washington, DC

Nutrition
Roberta James, MStat
Institute for Clinical Outcomes Research
Salt Lake City

16:50 Adjourn for the day

17:45 Reception

Greetings from Edward Eckenhoff, NRH President & CEO

Reception might include displays from sponsors, NRH Research, NRH Neuroscience Center, a pharmaceutical manufacturer, ISIS-ICOR, CERISE

18:30 Dinner

DAY 2

07:00 Breakfast

08:00 Stroke Rehabilitation Practice in New Zealand & the United States

Harry McNaughton, MD
Medical Research Institute of New Zealand
Wellington, NZ

08:50 The CERISE Study (5 centers in Europe)

Koen Putman, PhD
Free University of Brussels
Brussels, Belgium

Willy De Weerdt, MD
Katholieke Universiteit Leuven
Leuven, Belgium

09:40 Group Discussion on the International Dimension

Murray Brandstater, MD
Loma Linda, CA

10:05 Break

10:20 Workgroup Reports & Group Discussion
Moderator, e.g., Gerben DeJong, PhD (or possibly Alan Jette, PhD (Boston) if the budget allows)

Each workshop will present its findings/implications/recommendations followed by a brief Q & A from the audience followed by:
Implications for practice
Implications for accreditation standards
Implications for policy
Implications for future publications
Implications for future research & funding
Recommendations: What are the next steps?

12:15 Closing remarks

G DeJong, PhD
E Healton, MD

Project E2: **Expert Panel on Neuroprotectant Treatment of Mild Brain Injury**

Funding period: Year 3 of 1-year funding period

Status: Project is starting on June 21, 2005

Principal Investigators: Joseph Bleiberg, PhD

Abstract:

In the late 1970s and 1980s there was a rush of clinical trials using neuroprotectants as treatment for traumatic brain injury. Unfortunately, the initial excitement and optimism gave way to disappointment in the face of poor results, with several agents actually appearing to exacerbate the injury they were designed to treat. The present project will assemble a multidisciplinary group of experts to review newer generation neuroprotectants and determine whether there is a sound scientific rationale to reconsider a neuroprotectant clinical trial. Specifically, the panel will review candidate neuroprotectants in order to produce one of two actions: 1) a state-of-the-art literature review of neuroprotectants, with the conclusion that none are promising for current clinical trials, or, 2) the identification of one or more promising neuroprotectants, with the conclusion that a clinical trial should be undertaken. In the event of the latter conclusion, the literature review will serve as the introduction for a clinical trial research proposal.

Progress and Outcomes:

The Expert Panel will be chaired by James P. Kelly, M.D., Professor of Neurosurgery, University of Colorado Medical School. Edward Healton, M.D. and Alex Dromerick MD, will be members of the Panel. A Statement of Work has been agreed upon and a the subcontract has been signed with the University of Colorado to conduct the Panel.

Barriers and Solutions:
None remaining and the project will be completed this upcoming year.

Staffing changes:
Dr. Kelly, as noted above, will chair the Panel.

Plan: Unchanged with respect to Expert Panel. However, a dissemination plan for the results of the panel has been developed. It consists of applying for private funds to devote an Aspen Institute to the findings of the Panel. This is *in addition* to the original plan regarding publication. Dr. Kelly has been successful in creating several Aspen Institutes on brain injury in the past.

Appendix:

ASSISTANCE AGREEMENT

AWARD TYPE: ☐ GRANT (31 USC 6304) ☑ COOPERATIVE AGREEMENT (31 USC 6305) ☐ OTHER TRANSACTION (10 USC 2371)			
AWARD NO: DAMD17-02-2-0032 Modification P00007	EFFECTIVE DATE See Grants Officer Signature Date Below	AWARD AMOUNT	Page 1 of 1

PROJECT TITLE: NRH Neuroscience Research Center

CFDA 12.420

PERFORMANCE PERIOD: 1 June 2002 - 30 June 2006 (Research to be completed by 31 May 2006)	**PRINCIPAL INVESTIGATOR:** Alexander Dromerick, MD
AWARDED AND ADMINISTERED BY: U.S. Army Medical Research Acquisition Activity ATTN: MCMR-AAA-W 820 Chandler St. Fort Detrick Maryland 21702-5014	**PAYMENTS WILL BE MADE BY:** EFT:T Army Vendor Pay DFAS-SA/FPA 500 McCulbugh Ave. San Antonio TX, 78215-2100 *(SEE PARAGRAPH TITLED "PAYMENTS" FOR INSTRUCTIONS)*
DUNS No: 077366664 **TIN No:**	
AWARDED TO: National Rehabilitation Hospital 102 Irving Street, NW Washington, DC 20010-2949	**REMIT PAYMENT TO:** National Rehabilitation Hospital 102 Irving Street, NW Washington, DC 20010-2949

ACCOUNTING AND APPROPRIATION DATA:
N/A

SCOPE OF WORK:

1. Reference NRH Letter dated Oct 13, 2005, subject: Change of Principle Investigator for "NRH Neuroscience Research Center", is hereby incorporated into this award.

2. Paragraph 1.(c) Recipient Responsibility, the Principal Investigator is hereby approved and changed as follows:
From: Edward B. Healton, M.D. To: Alexander Dromerick, M.D.

3. As a result of this modification the total amount of this award remains unchanged.

RECIPIENT		GRANTS OFFICER	
ACCEPTED BY: Signature Not Required SIGNATURE		**UNITED STATES OF AMERICA** Cheryl R. Miles SIGNATURE	
NAME AND TITLE	**DATE**	**NAME AND TITLE** CHERYL R. MILES GRANTS OFFICER	**DATE** 11/16/05

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October 13, 2005

COL Mary S. Lopez, PhD, CPE, OTR/L
Manager, Ergonomics Program
United States Army Center for Health Promotion & Preventive Medicine
5158 Blackhawk Road
Aberdeen Proving Ground, MD 21010-5403

RE: Award No: **DAMD17**-02-2-0032
Change of Principle investigator for "NRH Neuroscience Research Center"

Dear COL Lopez:

As mentioned in the year three annual report for the NRH Neuroscience Research Center (NRC), we have recently hired Alexander Dromerick, MD to serve as Co-Director of the NRC. Dr. Dromerick is an experienced clinical investigator and has been the site PI for both industry and NIH funded studies. These studies have occurred in both the acute and rehabilitation setting. In addition, Dr. Dromerick is currently the PI of an NINDS Pilot Clinical Trial titled "Constraint-Induced Therapy within Days after Stroke" (NS41261-01A1). His expertise in developing, conducting, and leading research activities is a tremendous asset to NRH and The NRC.

Due to his vast experience, we have appointed Dr Dromerick as the Director of the NRC and PI for the NRC grant award. I will remain involved in the remaining year of the grant and assist Dr. Dromerick as need.

I have included the year three annual report that was submitted in July 2005 and Dr. Dromerick's CV for your reference.

Please contact me with any question regarding this request.

Sincerely,

Edward B. Healton, MD MPH
Senior Vice President and Medical Director
National Rehabilitation Hospital
(202) 877-1140 (Office)
and
Professor and Chairman
Department of Rehabilitation Medicine
Georgetown University Hospital

cc: Alexander Dromerick MD
Tom Dang MSE
Matt Elrod PT, MEd, NCS

Outcomes and Reimbursement of Inpatient Rehabilitation Facilities and Subacute Rehabilitation Programs for Medicare Beneficiaries With Hip Fracture

Anne Deutsch, PhD, RN, CRRN, Carl V. Granger, MD,† Roger C. Fiedler, PhD,‡ Gerben DeJong, PhD,§,§§ Robert L. Kane, MD,¶ Kenneth J. Ottenbacher, PhD,‖ Allen W. Heinemann, PhD,** John P. Naughton, MD,† and Maurizio Trevisan, MD††*

Objective: We sought to assess whether outcomes and reimbursement differ for Medicare beneficiaries with hip fracture when treated in an inpatient rehabilitation facility (IRF) compared with a skilled nursing facility (SNF) subacute rehabilitation program.

Participants: Clinical data were linked with Medicare claims for 29,793 Medicare fee-for-service beneficiaries with a recent hip fracture who completed treatment in 1996 or 1997 in rehabilitation facilities that subscribed to the Uniform Data System for Medical Rehabilitation.

Outcome Measures: We measured discharge destination, change in motor FIM™ rating, and Medicare Part A reimbursement.

Results: For patients with moderate-to-severe and severe disabilities, case mix groups (CMGs) 704 and 705, the percentage of patients discharged to the community from IRFs was lower than for patients treated in subacute rehabilitation SNFs, after controlling for covariates. Adjusted odds ratios were 0.71 (95% confidence interval 0.55–0.92) for CMG 704 and 0.72 (95% confidence interval 0.63–0.83) for CMG 705. For patients in the 3 other CMGs, no significant differences were detected. Improvement in motor functional status was roughly equivalent for patients treated in IRFs and those treated in the subacute rehabilitation programs across all 5 CMGs, after controlling for covariates. Medicare Part A payments for IRFs were significantly higher than SNF payments across all CMGs.

Conclusion: SNF-based subacute rehabilitation was less costly and outcomes were in most, but not all, instances similar or better than IRF-based rehabilitation for Medicare fee-for-service beneficiaries who had a recent hip fracture.

Key Words: hip fracture, rehabilitation, outcomes, reimbursement

(*Med Care* 2005;43: 892–901)

From the *Institute for Health Services Research and Policy Studies, Northwestern University, Chicago, Illinois; †Department of Physical Medicine and Rehabilitation, School of Medicine and Biomedical Sciences, University at Buffalo, The State University of New York, Amherst; ‡Planning and Evaluation, D'Youville College, Buffalo, New York; §NRH Research, National Rehabilitation Hospital, Washington, DC; ¶Health Services Research and Policy, University of Minnesota, Minneapolis; ‖University of Texas Medical Branch, Galveston; **Department of Physical Medicine and Rehabilitation, Feinberg School of Medicine, Northwestern University & Center for Rehabilitation Outcomes Research, Rehabilitation Institute of Chicago, Chicago, Illinois; ††School of Public Health and Health Professions, University at Buffalo, The State University of New York, Buffalo; and §§Department of Rehabilitation Medicine, Georgetown University School of Medicine, Washington, DC.

Supported by the Centers for Medicare and Medicaid Services (CMS), under the Dissertation Grant Program, Grant number 30-P-30247. This article was written while Dr. Deutsch was a postdoctoral fellow at the Institute for Health Services Research and Policy Studies under an institutional Advanced Rehabilitation Research award from the National Institute on Disability and Rehabilitation Research (Award Number H133P980014-02).

This work is an update from Dr. Deutsch's dissertation research and was presented at the American Congress of Rehabilitation Medicine and American Society of Neurorehabilitation 2003 Joint Conference in October 2003 in Tucson, Arizona. The conference abstract was published in *Archives of Physical Medicine and Rehabilitation*. 2003;84:A4.

Reprints: Anne Deutsch, PhD, RN, CRRN, Rehabilitation Institute of Chicago, 345 East Superior St., Chicago, IL 60611-3071. E-mail: a-deutsch@northwestern.edu.

ISSN: 0025-7079/05/4309-0892

Hip fracture is a common cause of hospitalization for the elderly and is associated with significant mortality, morbidity, and cost. Each year, an estimated 350,000 persons in the United States experience a hip fracture.[1] Approximately 4% of patients with hip fracture die during the acute care hospital stay, and an additional 10 to 35% die within 1 year of the injury.[2] At 1 year, approximately 73% of survivors recover basic activities of daily living (ADL) skills to their prefracture level, and 48% recover their prefracture instrumental ADL skills.[3] Health care costs during the first 6 months after a hip fracture are estimated to average $26,900 (2001 U.S. dollars), and the lifetime attributable cost of a hip fracture is approximately $81,300, of which 44% are nursing home costs.[4]

The delivery of health services to patients with hip fracture has changed since the early 1980s with the implementation of the Medicare prospective payment system (PPS)

in acute care hospitals, the growth of managed care, and medical and technological advances. As the average acute care stay decreased from 18.6 days in 1982[5] to 6.6 days in 2002,[6] use of postacute rehabilitation services increased.[7–9] Rehabilitation goals include fostering an individual's ability to manage his or her own daily activities and, as much as possible, returning the person to an active and productive life in a community-based setting.

Two major categories of providers of postacute inpatient rehabilitation services in the United States are Inpatient Rehabilitation Facilities (IRFs) and Skilled Nursing Facilities (SNFs). IRFs provide intensive rehabilitation services,[10,11] and some SNFs offer subacute rehabilitation programs, which provide "comprehensive but less intense" rehabilitation therapy services.[12] Since the early 1990s, the distinctions between IRFs and SNF-based subacute rehabilitation programs have diminished, and the most appropriate use of these 2 types of rehabilitation care based on outcomes and costs is unclear.[10]

Earlier studies have consistently shown that care in an IRF is more costly than care in a SNF.[8,13] With regard to patient outcomes, Kane et al[14] found that among patients who were healthy prior to the fracture, those treated in IRFs achieved the most functional improvement compared with patients receiving care in SNF-based rehabilitation programs or in standard nursing homes. For patients who had prefracture motor or cognitive deficits, functional improvement was not significantly different for patients discharged from IRFs, SNF-based rehabilitation programs and standard nursing homes. Kramer et al[13] reported that the percentages of patients with hip fracture living in the community following treatment in an IRF or SNF-based rehabilitation program was not different, and found no difference in ADL independence for patients treated in IRFs and SNFs. These studies provide some evidence about the relative effectiveness of IRFs and SNF-based rehabilitation programs; however, important questions regarding which setting provides cost effective care for specific subgroups of patients remain unanswered.

The purpose of this study was to compare the clinical outcomes and reimbursement of care provided in IRFs and SNF-based subacute rehabilitation programs for patients with hip fracture in the traditional (ie, nonmanaged care) Medicare program. The research questions were (1) Does the percentage of patients discharged to the community differ for IRFs versus SNF-based rehabilitation, after adjusting for potential confounders? (2) Does the short-term functional outcomes of patients treated in IRFs differ from those achieved by patients treated in SNF-based rehabilitation, after adjusting for potential confounders? (3) Do Medicare payments for patients treated in IRFs differ from Medicare payments for SNF-based rehabilitation care across all Case-Mix Groups (CMGs)?

METHODS

The project was approved by the Institutional Review Board at the University at Buffalo. Patient and facility data from IRFs and SNFs for the years 1996 and 1997 were obtained from the Uniform Data System for Medical Rehabilitation (UDSMR), a large and nationally representative rehabilitation outcomes measurement system. The patient records from UDSMR, a convenience sample, included sociodemographic, diagnostic, and stay data, including admission and discharge Functional Independence Measure (FIM™) instrument ratings. The FIM instrument is a functional assessment scale that includes 13 motor and 5 cognitive items. Each item is rated on a 7-level scale with "7" indicating complete independence, and "1" signifying total assistance. Investigations of the psychometric properties of the FIM instrument have found it to be reliable, valid, and responsive to change for rehabilitation patients.[15–18] UDSMR patient records were selected if the primary payer source was Medicare (nonmanaged care) and the primary impairment was hip fracture or the etiologic diagnosis was one of the hip fracture *International Classification of Diseases*, 9th edition, Clinical Modification (ICD-9-CM) codes: 820.0x to 820.9x.

The Centers for Medicare and Medicaid Services (CMS) provided Medicare Provider and Analysis and Review (MedPAR) files for IRFs and SNFs for the years 1996 and 1997. MedPAR files contained stay-level data for beneficiaries in the traditional Medicare program and included demographic, diagnostic, stay, and financial data. MedPAR records were selected if the hip fracture ICD-9-CM codes of 820.0x to 820.9x were reported as the admission diagnosis or one of the first 2 listed medical diagnoses.

The UDSMR and MedPAR data files were linked so that FIM data and reimbursement data for each patient were available in one record. A staged probabilistic matching algorithm[19] was used to link the data because no common patient identifier was available in both files. Within matched facilities, record pairs from the 2 sources were linked based on the agreement of information reported for 6 variables: admission date, discharge date, age, postal code, sex, and race/ethnicity. A median of 83% of IRF records and 83% of SNF records were linked. Details of the processes used to link the data are described elsewhere.[20]

A total of 35,454 patient records were linked to include both clinical (UDSMR) and payment (MedPAR) data. Because the focus of this study was to compare the outcomes of care, the records of patients with atypical or incomplete stays were excluded. Significantly higher percentages of SNF records were excluded because (1) patients were admitted from another rehabilitation facility (6.3% vs. 2.9%); (2) patients were discharged to an acute care unit (5.6% vs. 4.7%); (3) patients died during the rehabilitation stay (1.2% vs. 0.3%); (4) patients had a program interruption during the rehabilitation

stay (3.5% vs. 2.5%); (5) records were missing admission FIM data (0.5% vs. 0.1%); and (6) records were missing discharge FIM data (0.9% vs. 0.2%). Additional exclusion criteria that were applied and were the same for the 2 settings were patients who (1) were not living in the community before the fracture, (2) were admitted more than 60 days after the fracture, (3) had a rehabilitation length of stay (LOS) shorter than 3 days, and (4) had a rehabilitation LOS that was longer than 3 standard deviations above the mean of the logarithm of the LOS. After applying the exclusion criteria, 85.0% of the IRF records and 79.6% of the SNF records remained.

The final sample included 29,793 patient records, of which 83.0% of patient records (n = 24,714) were from 551 IRFs, and 17.0% (n = 5079) were from 234 SNFs.

The dependent variable in the first set of analyses was the patient's discharge destination reported in the UDSMR data, either a community or noncommunity residence. For the second set of analyses, the dependent variable was the patient's change in motor functional status, the difference between the sum of the 13 admission and discharge motor FIM ratings. The third dependent variable was the Medicare Part A payment to the facility.

The independent variable in this study was the type of rehabilitation setting in which the patient received treatment, either (1) an IRF or (2) a SNF-based subacute rehabilitation program. IRFs typically provide 3 hours of rehabilitation therapy at least 5 days a week, have frequent physician involvement, and 24-hour rehabilitation nursing care.[10,11] SNF-based subacute rehabilitation programs provide "comprehensive-but-less-intense" rehabilitation therapy services.[12] SNFs must have a physician who supervises care, a physician who is available 24 hours a day on an emergency basis, and 24-hour nursing services.[10,21] A table summarizing Medicare regulations for IRFs and SNFs is presented in the Appendix.

Covariates that have been shown to influence outcomes and included in regression models were: the time from the fracture to the rehabilitation admission, admission motor FIM rating,[22] admission cognitive FIM rating,[23,24] type of hip fracture repair (hip replacement or open/closed reduction with/without internal fixation),[25] presence of a tier 1, tier 2, or tier 3 comorbidity,[26] age,[2] prehospital living arrangement (alone or not alone),[27] median household income (assigned based on residential ZIP code),[28] sex,[29] race (white or nonwhite),[30] number of patients with hip fracture treated in the facility (ie, volume),[31] county managed care penetration percent (from the Area Resource File),[32,33] rural location,[34] facility profit status (profit or not-for-profit), facility type (facility in a hospital or freestanding facility),[26] and geographic location (New England, Middle Atlantic, East North Central, West North Central, South Atlantic, East South Central, West South Central, Mountain or Pacific).[8]

The outcomes models were estimated with and without LOS adjustment (transformed by its logarithm) to estimate the extent to which the observed outcomes may be related to LOS differences.

The CMG patient classification system, used in the Medicare IRF PPS, was used as a stratification variable. Patients with hip fracture are assigned into one of 5 CMGs based on the sum of the ratings for 12 FIM motor items: (1) 701 (least severely disabled): FIM-12 motor rating 52 to 84; and (2) 702: 46 to 51; 703: 42 to 45; 704: 38 to 41; 705 (most severely disabled): 12 to 37.[26,35]

Descriptive statistics were calculated to characterize the sample. Cronbach's alpha showed good internal consistency reliability[36] for motor and cognitive FIM item ratings in both IRFs and SNFs, with all values greater than 0.85.

Regression analyses were used to quantify the relationship between the type of rehabilitation setting and patient outcomes, after controlling for patient- and facility-level covariates. Most continuous covariates required transformation (eg, logarithmic, squaring). Logistic regression was used to test whether the percent of patients discharged to the community was different for IRFs and SNFs, and multiple linear regression was used to determine whether patients' change in motor function was different for IRFs and SNFs. Because small differences in motor FIM ratings may reflect some measurement error as well as true differences in functional status,[17] differences of 2 or more FIM units were regarded as clinically important for this study. This criterion was based on cross-sectional data correlating FIM ratings with caregiver assistance, which found that, on average, FIM scores that were lower by 2 units were associated with an increase of 6 to 10 minutes of caregiver assistance per day.[37,38]

Patient records were stratified into the 5 CMGs after regression analyses found significant interactions between the admission FIM ratings and the rehabilitation setting variable. Age and rehabilitation setting also produced an interaction effect; however, separate analyses by age across each CMG found similar results and are not reported.

The MedPAR reimbursement data include facility-specific adjustments. In this study, reimbursement data were standardized to reflect a wage index of 1.000, and no adjustments for indirect medical education, a disproportionate share of low-income patients, or rural location.[20] The 1996 data were adjusted for inflation to reflect 1997 U.S. Dollars. T-tests were used to determine whether Medicare Part A payments and patient payments made to IRFs and SNFs were different. To control for case-mix differences, comparisons of IRF and SNF payment data were made for each of the 5 CMGs. For all analyses, testing was 2-sided using an alpha of 0.05.

RESULTS

Table 1 shows that patients with hip fracture treated in IRFs were slightly younger (mean age was 80.4 for IRFs and

TABLE 1. Sociodemographic, Medical, and Stay Characteristics of Patients with Hip Fracture Who Completed* the Rehabilitation Program by Type of Rehabilitation Setting, 1996 and 1997

Characteristic	IRF (n = 24,714)	SNF Subacute Rehabilitation Program (n = 5079)	P
Mean age, yr (SD)	80.4 (8.2)	82.1 (8.1)	<0.001
Male, %	21.6	19.1	0.012
Race: Nonwhite, %	6.4	3.6	<0.001
Eligible for Medicare and Medicaid, %	8.4	6.4	<0.001
Married, %	33.0	29.7	<0.001
Lived alone, %	42.4	43.2	0.222
Mean time from onset to rehabilitation admission, days (SD)	7.2 (5.9)	8.0 (6.9)	<0.001
Mean length of rehabilitation stay, days (SD)	16.2 (8.0)	23.4 (15.2)	<0.001
Community discharge, %	81.3	81.4	0.947
Hip fracture repair (in acute care hospital), %			
Hip replacement	57.7	57.2	
Open or closed reduction with or without internal fixation	34.6	32.5	<0.001
Unknown	7.7	10.3	
Comorbidities/complications, %			
Tier 1 (most severe)	0.4	0.1	
Tier 2 (moderately severe)	3.8	2.6	<0.001
Tier 3 (mild)	9.4	6.3	
None of listed comorbidities	86.5	91.0	
Case-Mix Group distribution, %			
701 (mild disability)	18.6	17.6	
702 (mild-to-moderate disability)	24.6	21.3	
703 (moderate disability)	16.0	14.4	<0.001
704 (moderate-to-severe disability)	13.4	12.8	
705 (severe disability)	27.3	33.9	
Mean admission motor FIM™ rating† (SD)	44.8 (10.3)	42.8 (11.6)	<0.001
Mean admission cognitive FIM rating (SD)	28.8 (6.7)	28.3 (7.7)	<0.001
Mean discharge motor FIM rating (SD)	66.6 (13.4)	64.8 (15.9)	<0.001
Mean discharge cognitive FIM rating (SD)	30.3 (5.9)	29.6 (6.9)	<0.001

Significance levels were determined using t tests and χ^2 tests.
*As described in detail in the text, patients with atypical and incomplete stays were excluded from analyses.
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82.1 for SNFs), were more likely to be nonwhite (6.4% vs. 3.6%), and more likely to be Medicaid beneficiaries (8.4% vs. 6.4%) than SNF patients. These differences were observed for each CMG. IRF patients had slightly higher admission and discharge motor FIM ratings, indicating more independence with motor skills.

Table 2 shows that 24% of IRFs and 65% of SNFs were freestanding facilities. The geographic distribution varied, primarily in the West South Central region, where 17% of IRFs and 8% of SNFs were located. Approximately 72% of the IRFs and 39% of the SNFs were not-for-profit entities.

Community Discharges

Before adjusting for covariates, the percentages of patients discharged to the community from IRFs and SNFs for each CMG were calculated (Table 3). Among patients in CMG 702 and CMG 704, those admitted to SNFs were slightly more likely to be discharged to the community (89.4% for IRFs and 91.7% for SNFs, $P = 0.024$ for CMG 702; 79.3% for IRFs and 83.8% for SNFs, $P = 0.008$ for CMG 704). No statistically significant differences were detected for patients in CMGs 701, 703, and 705. After controlling for covariates, patients in CMG 704 and 705 who were treated in IRFs were slightly less likely to be discharged to the community (adjusted odds ratio = 0.71, 95% confidence interval [CI] = 0.55–0.92 for CMG 704 and 0.72, 95% CI = 0.63–0.83 for CMG 705) than patients treated in SNF-based programs. Differences for the other CMGs were not statistically significant. When LOS was added as a co-

TABLE 2. Characteristics of Facilities by Type of Rehabilitation Setting, Patients with Hip Fracture 1996 and 1997, (n = 785 Facilities)

Facility Characteristic	IRF (n = 551)	SNF Subacute Rehabilitation Program (n = 234)	P
Type of facility, %			
Freestanding	24.3	65.4	<0.001
Distinct unit/facility in a hospital	75.7	34.6	
Rural location, %	10.0	6.4	0.108
Geographic location, %			
New England	4.0	11.1	
Middle Atlantic	11.1	17.1	
East North Central	23.4	23.5	
West North Central	6.9	6.4	
South Atlantic	18.1	15.4	<0.001
East South Central	4.5	0.4	
West South Central	16.9	7.7	
Mountain	5.6	6.8	
Pacific	9.4	11.5	
Volume: Mean number of patients (all payers) in facility in 1997	52.3 (50.8)	33.9 (35.5)	<0.001
Managed care penetration: Mean percent managed care in county, %	27.5 (17.3)	32.9 (15.5)	<0.001
Facility ownership, %			
Government (federal, state, county, local)	6.9	2.6	
Not-for-profit	71.5	38.9	<0.001
For profit	21.6	58.5	

Significance levels were determined using t tests and χ^2 tests.

variate, only the adjusted odds ratio for CMG 705 was statistically significant (adjusted odds ratio = 0.84, 95% CI = 0.74–0.96, $P = 0.013$).

Change in Functional Status

Before adjusting for covariates, the mean changes in motor FIM rating for IRF and SNF patients were compared (Table 3). Among patients in CMG 702, the mean (SD) change in motor FIM rating for SNF patients was 22.9 (8.0), statistically significantly higher than IRF patients' ratings of 21.9 (7.2). A difference of 1 FIM unit is small and probably not clinically important. For all other CMGs the difference in FIM rating was not statistically significant.

After controlling for covariates, the difference in change in motor FIM rating was not different for any of the CMGs. When LOS was added as a covariate (Fig. 1), patients in 2 CMGs showed a statistically significantly greater change in FIM motor rating when treated in an IRF versus a SNF-based subacute program. The mean adjusted difference in rating change was 1.07 (95% CI: 0.33–1.81, $P = 0.004$) for CMG 703 and 2.07 (95% CI: 1.41–2.74, $P < 0.001$) for CMG 705. As noted previously, the difference for CMG 703 may not be clinically important.

Medicare Reimbursement

The mean unadjusted Medicare Part A payment per patient was $10,671 (1997 U.S. dollars) for IRFs, significantly higher ($P < 0.001$) than the $7433 for SNF-based rehabilitation programs. When payment amounts were standardized to remove facility-specific adjustments, the mean payment to IRFs was $11,069, and $7210 for SNF-based rehabilitation (Table 4), a difference of $3859 ($P < 0.001$). When payment data were analyzed separately for each CMG, the standardized Medicare Part A payments for IRFs remained statistically significantly higher across all 5 CMGs. Although IRF payments were higher than SNF payments, the mean IRF LOS was significantly shorter than the mean SNF stay for each CMG.

The percentages of beneficiaries with payments (deductibles and copayments) were 14% for IRFs and 48% for SNF-based rehabilitation programs. For IRF patients, the proportion with payments and the mean payment amounts were similar across all CMGs. For SNF patients, as functional dependence increased (ie, from CMG 701 to 705), the proportion of patients with payments increased from 26% to 59%, and the mean (SD) payments increased from $263 (698) to $1078 (1575).

TABLE 3. Percent of Patients Discharged to the Community, Adjusted Odds Ratio for Community Discharge, Mean Change in Motor FIM Rating and Adjusted Mean Difference in Motor FIM™ Change for Patients with Hip Fracture Treated in IRFs and Subacute SNFs by Case Mix Group, 1996 and 1997

CMG	No. Patients		Percent of Patients Discharged to the Community (Unadjusted)		Adjusted* Odds Ratio for Community Discharge (95% CI)	Mean (SD) Change in Motor FIM™ Rating (Unadjusted)		Adjusted* Mean Difference (IRF minus SNF) in Motor FIM Rating (95% CI)
	IRF	SNF	IRF	SNF		IRF	SNF	
701	4603	896	94.8	94.0	1.10 (0.78–1.56); $P = 0.576$	18.3 (6.3)	18.8 (7.0)	−0.11 (−0.55 to 0.33); $P = 0.624$
702	6078	1080	89.4	91.7	0.80 (0.62–1.04); $P = 0.096$	21.9 (7.2)	22.9 (8.0)	−0.14 (−0.64 to 0.35); $P = 0.571$
703	3964	730	84.2	85.1	0.93 (0.72–1.20); $P = 0.586$	23.4 (8.8)	23.6 (9.6)	0.60 (−0.13 to 1.34); $P = 0.107$
704	3316	650	79.3	83.8	0.71 (0.55–0.92); $P = 0.009$	24.1 (9.9)	24.9 (10.2)	−0.27 (−1.14 to 0.61); $P = 0.547$
705	6753	1723	64.2	65.9	0.72 (0.63–0.83); $P < 0.001$	21.9 (12.3)	21.3 (13.8)	−0.16 (−0.85 to 0.53); $P = 0.650$

Odds ratios and associated significance levels determined using logistic regression. C statistic values were: 0.738 for 701, 0.717 for 702, 0.688 for 703, 0.697 for 704, and 0.671 for 705. Adjusted mean difference in motor FIM rating and associated significance levels determined using multiple linear regression. Adjusted R^2 values were: 0.269 for 701, 0.140 for 702, 0.137 for 703, 0.145 for 704, and 0.169 for 705.

*Adjusted for the time from the fracture to the rehabilitation admission, admission motor FIM rating, admission cognitive FIM rating, type of hip fracture repair, presence of a tier 1, tier 2 or tier 3 comorbidity, age, pre-hospital living arrangement (alone or not alone), median household income (assigned based on residential ZIP code), sex, race (white or non-white), number of patients with hip fracture treated at the facility (ie volume), county managed care penetration percent, facility rural location, facility type, facility profit status and geographic region.

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DISCUSSION

This study examined the outcomes and reimbursement for Medicare fee-for-service beneficiaries who completed a stay in an IRF or SNF-based subacute rehabilitation program in 1996 and 1997. Analyses included only facilities that submitted data to UDSMR and that was matched to MedPAR data. IRFs provide intensive rehabilitation treatments to patients over a shorter course, whereas the SNF-based subacute rehabilitation programs provided varying levels of treatments typically over a longer period of time.

The percentages of patients discharged to the community from IRFs and SNF-based rehabilitation programs were not different for 3 of the 5 CMGs, after controlling for covariates. For patients with moderate-to-severe and severe disabilities (CMGs 704 and 705), community discharge was slightly higher for patients treated in SNF-based subacute programs compared with patients treated in IRFs. Change in motor FIM ratings for patients treated in IRFs and SNF-based rehabilitation programs were not different for any of the CMGs, after adjusting for covariates. When LOS was added as a covariate, functional improvement for patients in CMG 705 was greater for IRF patients compared with SNF patients. This may mean that the longer SNF stay was needed to achieve similar functional gain in the 2 settings for these patients. Medicare Part A payments to IRFs were significantly higher than payments to SNFs for patients with hip fracture across all CMGs.

The current study found that motor functional improvement was similar for patients in the 2 treatment settings across all severity groups when adjusting for covariates. Kramer[13] also found no significant differences in the number of ADL difficulties for patients treated in IRFs and SNFs across 6 strata. Kane[14] found that healthier patients achieved more independence if treated in an IRF. Kane's finding is different than the current study; however, Kane grouped patients based on prefracture health status and the current study based on rehabilitation admission severity level.

Several limitations should be considered when interpreting study results. First, the facilities in the study voluntarily submitted their data to a national rehabilitation database; they were not selected randomly. This study included approximately 60% of the IRFs in the United States, but only 11% to 25% of SNFs that provided subacute rehabilitation services.[39,40] Carter[41] reported that Medicare patients in UDSMR's IRF database are representative of Medicare patients. The characteristics of SNF patients in this study were similar to the characteristics of SNF patients reported by Kane[14] and Kramer.[13] However, the SNFs included in this study were probably more focused on rehabilitation services than other SNF-based rehabilitation programs that did not submit data to UDSMR, a rehabilitation database. The results of this study cannot be generalized to all SNFs or to all SNF-based rehabilitation programs.

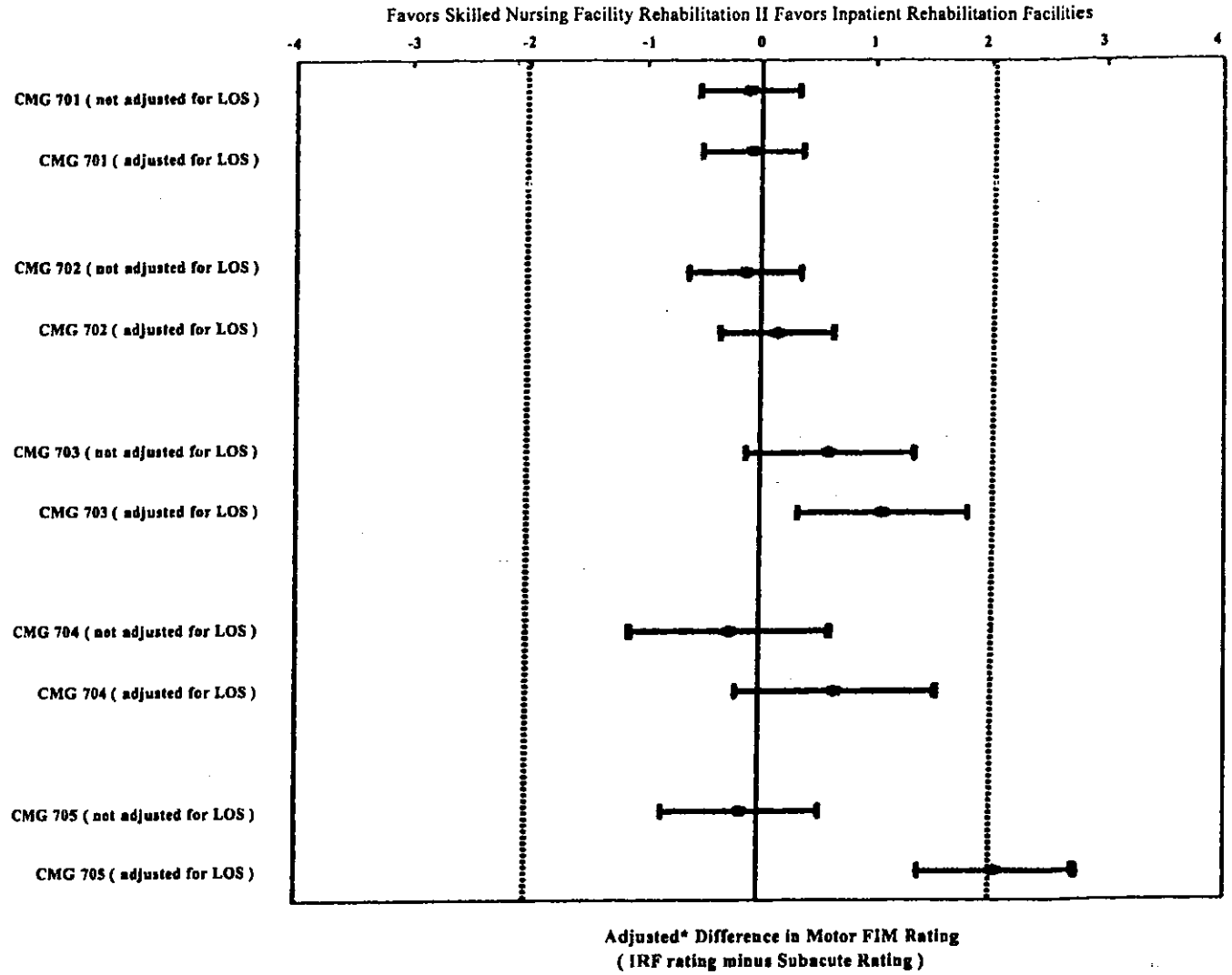

FIGURE 1. Adjusted difference in change in motor FIM™ ratings and 95% confidence interval for patients with hip fracture treated in IRFs and SNF subacute rehabilitation programs by case mix group with and without length of stay as a covariate, 1996 and 1997. Adjusted for the time from the fracture to the rehabilitation admission, admission motor FIM rating, admission cognitive FIM rating, type of hip fracture repair, presence of a tier 1, tier 2 or tier 3 comorbidity, age, prehospital living arrangement (alone or not alone), median household income (assigned based on residential ZIP code), sex, race (white or nonwhite), number of patients with hip fracture treated at the facility (ie, volume), county managed care penetration percent, facility rural location, facility type, facility profit status and geographic region. LOS is included as a covariate as indicated in the label. FIM is a trademark owned by UB Foundation Activities, Inc. CMG indicates case mix group; LOS, length of stay.

A second issue related to the generalizability of results is that the data are from 1996 and 1997, prior to the implementation of the Medicare PPSs in SNFs and IRFs. Clinical practices in IRFs and SNFs likely changed with new PPS-related incentives, with unknown effects to patient outcomes and payments. Thus, this study provides documentation of patient outcomes and reimbursement prior to the implementation of the PPSs.

The SNF PPS uses a per diem payment unit; therefore, SNFs have an incentive to minimize daily costs. Early studies examining the effects of the SNF PPS have suggested that patients may now be receiving less daily rehabilitation therapy.[42] The IRF PPS, a per-discharge payment system, creates an incentive to minimize costs during the entire IRF stay. Because Medicare has guidelines for the minimum amount of daily therapy in IRFs, length of stays may be shortened. Studies of the impact of the recently implemented IRF PPS have not yet been reported.

Third, this study used an observational design; patients were not assigned randomly to the rehabilitation settings. A

TABLE 4. Medicare Part A Payments, Patient Payments, and Length of Rehabilitation Stay for Patients with Hip Fracture Treated in IRFs and Subacute SNFs by Case Mix Group, 1996 and 1997

	No. Patients		Mean (SD) Standardized* Medicare Part A Payment, 1997 U.S. Dollars		Mean Length of Rehabilitation Stay		Percent of Patients With Payments		Mean (SD) Patient Payment: Deductibles and Co-payments, 1997 U.S. Dollars	
CMG	IRF	SNF	IRF	SNF	IRF	SNF	IRF	SNF	IRF	SNF
701	4603	896	7,942 (4377)	5,177 (3523)	12.2 (5.8)	16.7 (10.6)	15.4	25.7	125 (420)	263 (698)
702	6078	1080	9,624 (5230)	6,461 (3946)	14.5 (6.7)	21.2 (12.6)	14.4	44.3	123 (425)	509 (943)
703	3964	730	11,186 (5919)	6,865 (4080)	16.3 (7.1)	23.2 (14.7)	13.4	46.6	112 (375)	683 (1213)
704	3316	650	12,290 (6532)	7,619 (4885)	17.8 (8.0)	25.2 (14.3)	14.0	54.8	138 (520)	757 (1147)
705	6753	1723	13,832 (7641)	8,727 (6119)	19.5 (9.3)	27.8 (17.5)	14.7	59.3	150 (593)	1,078 (1575)
All CMGs	24,714	5079	11,069 (6497)	7,210 (5030)	16.2 (8.0)	23.4 (15.2)	14.4	47.8	131 (482)	715 (1259)

*Medicare Part A payment data were standardized to reflect to reflect a wage index of 1.000, and no adjustments for indirect medical education, a disproportionate share of low-income patients, or rural location, and 1996 data were adjusted for inflation to reflect 1997 U.S. Dollars.

For each CMG, mean standardized Medicare Part A payments, mean patient payments and mean length of stay for IRFs and SNFs were significantly different with $P < 0.001$ using t test.

variety of factors play a role in determining the setting where patients receive rehabilitation services, such as the severity of the patient's impairment, the availability of facilities in a geographic region, and physician and patient preferences. Although many covariates were considered in this study, data for many other factors, such as social support, nutritional status, and unrecorded comorbidities, were not available and thus not included in analyses. The possibility of sample selection bias was examined by calculating propensity scores that predicted the probability a patient would be treated in an IRF and stratifying the records into 5 equal groups based on the propensity scores. Among the patients who were least likely to be admitted to an IRF, the percentage of community discharges was lower among IRF patients compared with SNF patients (adjusted odds ratio was 0.68, $P = 0.001$). This group, which included many CMG 705 patients, tended to be older, had lower admission motor function, few comorbidities, and higher household income levels. For the other 4 quintiles, differences were not significant. The change in motor FIM rating was not statistically different for any of the quintiles. A fourth limitation of this study is that it included Medicare fee-for-service patients. Data for beneficiaries in the Medicare+Choice program were not available in the MedPAR files, and their experiences may have been different. Although analyses are based on ordinal-level FIM ratings, use of Rasch-transformed FIM motor and cognitive measures[43] did not alter results or conclusions.

This study focused on only one phase (ie, the inpatient rehabilitation component) of patients' recovery after a hip fracture. The functional status and outcome data were available only at rehabilitation admission and rehabilitation discharge; follow-up data were not available. In addition, instrumental activities of daily living data were not available as an outcome measure.

This study only examined Medicare Part A payments. It did not consider services that were paid by Medicare Part B. Part B physician payments, which would be expected to be higher for IRFs than for SNFs, and payments billed to Medicare Part B for ancillary services provided in some SNFs, were not available for analyses. Thus, the payment data do not represent total payments to providers from Medicare. Lui,[44] in analyzing 1990 Medicare claims, found that the mean charges to Medicare Part B for all beneficiaries (ie, all diagnoses) during SNF stays (both standard SNF and SNF-based rehabilitation) was approximately $1460.

Practice and Policy Implications

The Medicare program has responsibilities to its beneficiaries and to U.S. taxpayers to be a prudent purchaser of health care services. In setting policies, Medicare must try to balance access to services that result in the best long-term outcomes for the beneficiaries with the cost of such services.

The results of the current study suggest that for Medicare beneficiaries in the traditional plan who had a recent hip fracture, treatment in an IRF was more costly than treatment in a SNF-based subacute rehabilitation programs, and outcomes were similar or better in the subacute program. For patients with moderate to severe and severe disabilities, treatment in the less costly subacute rehabilitation SNF resulted in a slightly higher percentage of patients discharged to the community with equivalent functional improvement.

If pre- and post-PPS outcomes are similar, and if longer-term outcomes and costs are similar for patients discharged from both settings, directing patients with hip fracture to SNF-based subacute rehabilitation programs may result in cost savings for the Medicare Part A program.

Several barriers may limit implementation of the study conclusions, including (1) the availability of SNFs that offer subacute rehabilitation services, (2) the ability to distinguish SNFs that provide quality rehabilitation programs from standard SNFs, and (3) new incentives created with the implementation of PPSs in IRFs and SNFs, which may alter admission criteria, treatments and patient outcomes.

Comparing the outcomes and costs of rehabilitation care continues to be an important research topic now that all post acute care providers are paid by Medicare under PPSs. Researchers are also trying to identify why some patients achieve better outcomes–more specifically, what aspects of the rehabilitation program (eg, nature and intensity of treatments, role and qualifications of staff members, etc.) lead to variation in patient outcomes.[45,46] This work may enable researchers to move beyond the IRF-SNF dichotomy and examine more carefully the specific features and interventions of both that shape outcomes. We have yet to determine what is more important: Where the patient received care or what care the patient actually received, or both. We need to look beyond the setting of care to the active ingredients of both settings that make a difference in patient outcomes. A better understanding of the "active ingredients" offered in each setting should help influence referral and payment decisions that maximize cost-effective outcomes.[47]

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APPENDIX. Medicare Regulations for IRFs and SNFs in 1996–1997

Issue	IRFs	SNFs
Eligibility for admission	Eligibility determined by a physician	Patient must have had a hospital stay of at least 3 d in the 30-d period before the SNF admission
Maximum length of stay	90 d; 60 reserve days may be used once in a lifetime	100 d
Cost-sharing requirements in 1997	Deductible: $760/spell of illness Co-insurance: $190 daily starting on 61st day; if reserve days are used, $380 daily for days 91 through 150.	No deductible Co-insurance: $95.50 daily starting on 21st day
Medical conditions treated	75% of patients (all payers) must have at least 1 of 10 rehabilitation diagnoses (neurologic or musculoskeletal conditions, burns)	No regulations
Physician involvement	Patients must require frequent physician involvement	SNFs must have a physician who supervises care and a physician who is available 24 h a day on an emergency basis
Nursing care	Patients must require 24-h rehabilitation nursing care	SNFs must have sufficient staff to provide 24-h nursing services
Other allied health professions	Patients must require a coordinated group of skilled professionals	Dietary, pharmaceutical, dental and medical services must be available
Therapy hours required	Patients need intensive rehabilitation therapy (ie, 3 h at least 5 d a week)	No regulations
Medicare reimbursement guidelines in 1996 and 1997	IRFs were reimbursed on a cost-related basis subject to per-discharge limits.	Routine costs paid on an actual cost basis up to a per diem limit, ancillary services paid on a reasonable basis, and capital costs paid on a pass-through basis. Ancillary services not directly provided by SNF (ie, independent contractor) could be paid under Medicare Part B

Editor's note: This Commentary is based on a presentation made by Dr DeJong at a Conference on "New Rehabilitation" at the Allan Bean Centre in Christchurch, in March 2003. It is timely for New Zealand researchers and rehabilitation providers, as the emphasis on evidence-based practice continues. For those interested in this area, go to the New Zealand Guidelines Group website www.nzgg.org.nz.

RANDOMIZED CONTROLLED TRIALS IN REHABILITATION RESEARCH

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A common refrain in health care today is that the practice of health care should be based on well-established scientific evidence. Advocates of evidence-based practice—and we count ourselves among them—argue that practice variations from one geographic area to another and from one clinical setting to another are often an artifact of conditions on the supply side of the market. These may include the numbers and types of providers rendering care, their training, their clinical traditions and beliefs, and their clinical experience. Some observers remark that only about 20% of health care practice is based on unqualified scientific evidence, contrary to the public perception that medicine and its related disciplines are anchored in science.

In response to these observations, we now observe a nearly worldwide call for evidence-based practice. The clinical and health services research communities have come to accept hierarchies of evidence where randomized controlled trials (RCTs) are considered the highest level of evidence and anything less than RCT-level evidence is considered somewhat suspect.

RCT-level evidence presents a particular challenge for rehabilitation practice. Rehabilitation practice does not lend itself well to RCT research designs. RCTs work relatively well when there is a single intervention or a couple of interventions under study as in the case of a pharmaceutical intervention. Rehabilitation is an intrinsically multi-factoral intervention where it is difficult to isolate the contributions of individual interventions. Moreover, providers customize rehabilitation to the perceived needs of the individual resulting in even greater practice variation.

RCTs require that we hold all variables constant except the intervention under study in order to isolate the effects of the intervention and to reduce "noise" in the data. One result is that the intervention setting can become somewhat artificial and may not reflect what would otherwise transpire under less-controlled circumstances.

Another problem is that the selection criteria for participation in the study are often quite restrictive in order to reduce noise stemming from differences among study participants. Restrictive selection criteria limit the generalizability of the study's findings ("external validity") to the types of individuals represented in the study. The study's findings may not apply to the types of individuals excluded from the study. For example, many studies exclude individuals with comorbidities when significant comorbidities are common in many rehabilitation populations.

Restrictive selection criteria can also result in studies with very small numbers—drawn from a much larger pool of otherwise eligible participants. This makes real differences more difficult to detect and requires a larger effect size to achieve statistically significant differences. Enormous resources must then be expended in participant recruitment in order to locate individuals who meet the selection criteria.

Finally, RCTs assume some degree of "blinding." Double blinding means that neither the participant nor the researcher is aware of what is the actual intervention as in the case of a drug and its placebo. Rehabilitation interventions are not so easily disguised.

All of this leaves rehabilitation in a real bind. On the one hand, rehabilitation practice needs the legitimacy that sound scientific evidence can provide. On the other hand, its highly customized multi-factoral approach does not lend itself well to RCTs that require a more limited set of interventions and selection criteria that can make participant recruitment exhaustive and expensive. We could quickly exhaust the world's entire biomedical research budget in a given year to study all the variations and interventions in rehabilitation around the world.

This state of affairs presents a real challenge to a country such as New Zealand, a nation of 3.8 million people. Just three RCTs, or even fewer, could exhaust the nation's entire budget for rehabilitation research in any given year.

This means that one needs to look for alternative research designs that embrace variations in study population and interventions. Clinical and biomedical researchers appear obsessed with control through randomization when we have known for years that considerable control can be achieved statistically without randomization. We can determine, for example, how much of the variation in outcome may be due to individual participant differences and how much may be attributed to individual interventions or combinations of interventions or their joint effects—provided that the sample size is sufficiently large. The RCT paradigm, as we noted, focuses on a single intervention that may vary somewhat in dosage and small sample sizes may also restrict our ability to identify the types of individuals who are most or least likely to benefit from an intervention.

The multivariate approach is the one that we are now using in a large study on stroke rehabilitation interventions and outcomes at the Wellington and Kenepuru Hospitals. The study entails the participation of 200 individuals with stroke at the Wellington and Kenepuru hospitals and 1200 individuals with stroke at six rehabilitation centres in the U.S. The New Zealand site director is Harry McNaughton, MD and is funded in part through a grant from the National Institute on Disability & Rehabilitation in the U.S. The study's large sample size allows one to evaluate the contribution of multiple interventions and allows one to generalize to broader populations of stroke than would a more narrowly construed RCT. The study is also an example of how New Zealand can leverage its limited rehabilitation research resources in order to obtain meaningful research results with real clinical practice implications.

Large multivariate studies present their own challenges, however, that are not trivial. They require the ability to characterize and measure individual differences through severity or case-mix adjustment and the ability to characterize and measure all the treatment interventions—no small task given the somewhat ill-defined nature of rehabilitation interventions.

In our view, RCTs in rehabilitation research should be limited to less complicated interventions such as an exercise regime conducted on an outpatient basis or in a person's home. It should also be limited to "confirmatory analyses." This means that RCTs should be reserved to validate those hypotheses or findings that have been vetted through multivariate approaches. One also can, however, validate findings from multivariate studies by replicating the study or by implementing practice changes suggested by multivariate studies and then observing whether the predicted differences did indeed occur.

Because RCTs remain very much the gold standard of evidence in biomedical and clinical research, there has been a rush in some quarters to conduct RCTs without adequate consideration as to whether the research question or

hypotheses is truly RCT-ready. We believe that multi-million dollar RCTs should be undertaken only in the most compelling circumstances—and those circumstances are fewer than is commonly assumed.

For the foreseeable future rehabilitation research will remain in the shadow of other biomedical and clinical research enterprises because its armamentarium of interventions cannot be reduced to single bullet suited to an RCT. It will take a while—a long while—for multivariate, statistically controlled methods to obtain the degree of legitimacy that we currently accord RCTs. This state of affairs is no reason not to proceed, in the interim, with approaches more suitable to rehabilitation's multi-factoral approach.

Medicare Reform and the American Devolution

Gerben DeJong

The Medicare Modernization Act of 2003 (MMA'03) did more than introduce a prescription drug benefit for Medicare beneficiaries; it also laid the groundwork for several far-reaching changes in the Medicare program. These changes must be considered in the context of the "American devolution"—a much larger shift in American health and social policy that is changing how Americans manage their health and wealth as more tasks and responsibilities devolve to individuals in managing their personal affairs and their lives in the workplace. The devolution presents a special challenge to those who have diminished capacities for self-direction, including many stroke survivors who are especially dependent on the Medicare program for their rehabilitation and management of their diminished health status. This article calls for a massive investment in information technology and brokerage that will enable all Americans to effectively navigate the brave new world that the changes in the Medicare program portend. **Key words:** *devolution, information brokerage, Medicare, Medicare Modernization Act, prescription drugs, rehabilitation, stroke*

On December 8, 2003, the President signed into law the Medicare Prescription Drug Improvement and Modernization Act of 2003, commonly cited as the Medicare Modernization Act of 2003 (MMA'03). To most people, this 680-page bill is known for adding a long-awaited prescription drug benefit to the Medicare program. The Act actually represents a new divide in American social policy for older and disabled Americans that is not well understood. It is a divide that places a much higher burden on individuals in navigating information and making complex choices about health and income benefits that even the best-educated and most-informed persons are not well-equipped to make. For those with less education and less capacity for processing information, MMA'03 will be especially burdensome. For many people who have had a stroke, the choices will be especially difficult to navigate.

In this article, I want to focus less on the specific provisions of the MMA'03 and more on the larger trends that shape American health and social policy and what they mean for American individuals and families as they think about their future and plan for their older years. I will argue that the MMA'03 is part of a larger shift in the American economy that is only now affecting the twin towers of Social Security and Medicare. The new challenges that face Americans in general are particularly daunting for those who must cope with the limitations that arise from having had a stroke.

Main Provisions

What are some of the main provisions of MMA'03 that shape the choices facing older Americans and individuals with disabilities? There are four provisions or benefits that will eventually touch every American in one form or another: (a) the new prescription drug benefit, (b) new funding for Medicare managed care, (c) the premium support demonstration, and (d) health savings accounts. There are numerous other provisions aimed at providers, health plans, durable medical equipment vendors, and others. There are also provisions that address health care quality, the interface between Medicare and Medicaid, the development of care coordination demonstration

Editor's Note: This article reaches well beyond stroke rehabilitation to touch on how changes in the Medicare program are emblematic of larger changes that affect all of us. Dr. DeJong provides new insights about how these changes shape the lives of stroke patients, the work of service providers, and the roles that we have as individuals responsible for managing our personal and professional affairs.

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projects for those with chronic health conditions, temporary fiscal relief for academic health centers, and a wide range of esoteric payment issues of concern mainly to providers and health plans. This article is written primarily from the vantage point of a prospective Medicare beneficiary and less from the perspective of providers and health plans.

Collectively, the new Medicare provisions represent the most significant change in the scope of the Medicare program since the program's inception in the mid 1960s. Yes, in 1988, Congress did pass the Medicare Catastrophic Coverage Act that provided an outpatient drug benefit and catastrophic coverage for extended hospital stays. This act was, however, repealed a year later when well-to-do seniors rebelled after they found themselves paying for a benefit that was expensive and accrued mainly to those of lower socioeconomic status. This experience, as I note later, also shaped the prescription drug benefit provided in the MMA'03.

Prescription drugs

The prescription drug benefit, now Part D of the Medicare program, is the most widely advertised provision of MMA'03. It was touted by the Bush Administration during the 2004 election to gain a stronger foothold among seniors who were prone to view Medicare as a signature Democratic policy issue. The Administration wanted in on the Medicare franchise that had been long associated with Democrats, much like the Clinton Administration had usurped the welfare reform issue that had long been associated with Republicans a decade earlier. The White House was so determined and the House vote was so close that the roll call vote on the bill continued for 3 hours during the middle of the night (November 22, 2003) until enough Republican votes could be secured in an arm-twisting 220 to 215 vote that remains controversial to this day.

The prescription drug benefit features several controversial provisions. Most controversial is the structure of the benefit itself. Unlike most health benefits, the main deductible oddly occurs near the middle of benefit not at the front-end where the heavy deductibles usually appear, resulting in an odd contribution-and-benefit structure (see also **Figure 1**):

- A $35 per month premium.
- A $250 deductible.
- A 25% copayment from $251 to $2,250 of total drug costs.
- A $2,850 deductible or gap in coverage from $2,250 to $5,100 of total drug costs. This gap cannot be filled by a Medigap plan or by Medicaid coverage, and employer contributions will not count toward meeting out-of-pocket expenditures. This $2,850 gap is com-

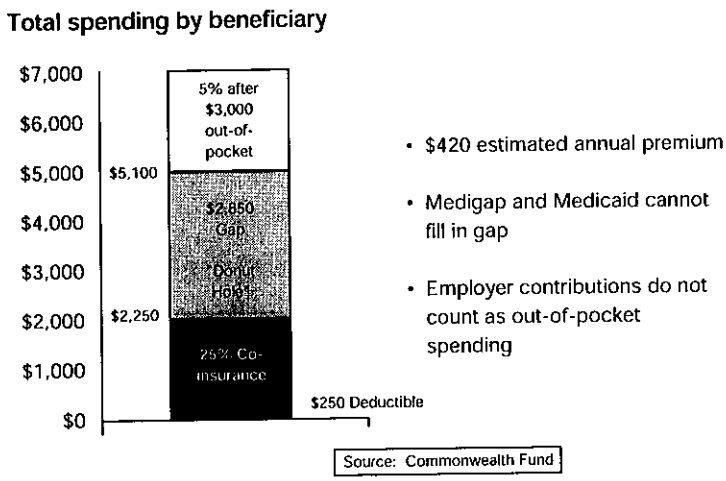

Figure 1. Prescription drug benefit 2006: beneficiary cost-sharing.

monly referred to as the "donut hole" in the benefit.
- A 5% copayment for amounts over $5,100 per year. In other words, this part of the benefit kicks in once the beneficiary has incurred a total of $3,600 in out-of-pocket expenses.

This odd benefit structure can be attributed to three factors. First is the experience of the 1988 Catastrophic Coverage Act cited earlier. This act was highly redistributive and only a few people received any benefit at all, which thus undermined any sustainable political constituency for the program. With the prescription drug benefit, Congress wanted to make sure that a lot of people received at least some benefit, no matter how small, in order to avert the kind of backlash seen 15 years earlier with the repeal of the 1988 Catastrophic Coverage Act. Second, Congress wanted to retain the catastrophic protection feature of the plan in keeping with basic insurance principles (premium for low-incident but high-cost events, not for ordinary and predictable events). And third, Congress wanted to keep the cost below a 10-year $400 billion price tag—a price tag that would appeal to fiscal conservatives but that later proved to be a phony one. As odd as this benefit may appear, its features and complexity mirror a larger trend in health and income benefits to be discussed later.

The prescription drug benefit becomes effective in January 2006 with enrollment beginning in 2005. Seniors will have a powerful incentive to sign up, because beneficiaries who delay enrollment after the initial enrollment period will face a 1.0% premium increase for each month of delay. One purpose of this provision is to avert "adverse risk selection" that is prone to occur when only those who perceive a need for the benefit sign up and those who do not perceive a need do not sign up. In other words, high-need beneficiaries self-select into the program, which creates a pool of higher cost beneficiaries that force health plans and prescription drug plans to raise premiums and thus make the benefit all but unaffordable to the large mass of beneficiaries. The cost of participation may, however, go up if the Centers for Medicare and Medicaid Services (CMS) determine that the actuarial costs are higher than projected. Moreover, the program contains low-income provisions designed to assist those who are dually eligible for Medicare and Medicaid and those who are not eligible for Medicaid but have incomes that hover near the federal poverty line. Complicating matters further are provisions that allow employer-sponsored retiree prescription drug benefits to be supplemented with Medicare dollars.

Bowing to the presumed competence and efficiency of the private sector, Congress provided that the drug benefit be administered through private prescription drug benefit management companies (PBMs) or through health maintenance organizations (HMOs) that participate under Part C of the Medicare program, now relabeled *Medicare Advantage*. The federal government will offer a Medicare prescription drug plan of its own in those geographic regions that fail to attract participation by a PBM or a Medicare HMO. When choosing a drug benefit plan, seniors will also have to consider the drug formularies that PBMs and Medicare HMOs offer to make sure that the drugs they need are included on the formulary. Drug formularies are not straightforward. Formularies, as well as classes of drugs within a formulary (e.g., beta blockers), can be "open" or "closed." Moreover, some drugs may be on the formulary but may require preauthorization. PBMs and HMOs may change their formularies at will, which adds to the uncertainty for seniors.

Until 2006 when the prescription drug benefit becomes effective, Congress has provided for a transitional drug discount card that will enable beneficiaries to experience some fiscal relief. Although the transitional drug benefit will have ended by the time this article is published, the experience of the transitional drug benefit has much to tell us about the administration of the Medicare drug benefit. Congress insisted that there be choice, but with choice comes the need for information. With many drug discount cards to choose from, CMS established a telephone hotline and a website where seniors could compare prices within their geographic area. Many seniors obtained incorrect information from the hotline and found that the website information was not always up to date. We will return to this experience later in the article.

Two other features of the drug benefit are worth

noting. First, Congress, in deference to the drug lobby, refused to authorize CMS to use the clout of its large purchasing power to negotiate lower prescription drug prices for its 41 million Medicare beneficiaries much like the Department of Veterans Affairs does on behalf of veterans. A Republican Congress believed that the market competition between PBMs and HMOs would lower prices without questioning why competition in today's markets had failed to do so. Second, Congress, in deference to vocal senior groups, allowed for the reimportation of drugs from Canada where prices for the same drugs are cheaper but essentially nullified the provision when requiring, in deference to the pharmaceutical lobby again, that the Department of Health and Human Services (HHS) certify the safety of such drugs. Thus far, HHS and the FDA have refused to provide such certification, thus rendering the drug reimportation provision moot.

Medicare Advantage (Medicare managed care)

Congressional Republicans and some Democrats have long believed that managed care in the form of HMOs would bring fiscal discipline to the Medicare program and added several sweeteners to the MMA'03 to induce greater participation by HMOs in the Medicare program, many of whom had exited the program in recent years. Recall that in the 1990s HMOs stepped up their participation in the Medicare program and doubled their share of the Medicare market from 8% at mid decade to 16% by the end of the decade (see **Figure 2**). Previously, Medicare paid HMOs a premium that was 95% of the amount spent on traditional or fee-for-service (FFS) Medicare on the presumption that HMOs would manage their patients more efficiently. At first, HMOs did well even when offering a prescription drug benefit mainly because it was able to appeal on average to younger and healthier Medicare beneficiaries. As the program succeeded and grew, its subscriber mix changed and HMOs could no longer make the margins they once did and began withdrawing from the Medicare market.

To reverse this trend, Congress agreed to have Medicare pay HMOs 100% of the amount spent by FFS Medicare and created a $10- to $12-billion slush fund for HMOs referred to as a *stabilization fund* that would be used to shore up HMO participation in the Medicare market. The actual amounts Medicare will pay HMOs will be between 108% and 116% of the amount spent for FFS Medicare.[1,2] These provisions have led some critics to dub the MMA'03 as the "No HMO Left-behind Act of 2003." These provisions will not be transparent to seniors except that seniors will see more choices including HMO options that had become less available to them in recent years. To seniors, these choices will come under the rubric of Medicare Advantage that previously had been known to them as Medicare + Choice. For seniors, the choice, unfortunately, will be little more than an old wine in a new bottle.

If the HMO sweeteners do result in a resurgence of Medicare managed care, we may well see a situation similar to the mid 1990s when Medicare HMOs were in their ascendancy and redefined much of the postacute rehabilitation landscape because of HMOs' preference for skilled nursing facilities (SNFs) over hospital-based rehabilitation facilities as the venue for rehabilitation. In the case of stroke rehabilitation, for example, we may see a resurgence of SNF-based rehabilitation as we had in the 1990s until HMOs started to withdraw from the Medicare market. Since then, stroke rehabilitation patients have returned to the traditional venue of hospital-based rehabilitation centers. Since 1998, many hospital-based SNFs found stroke rehabilitation patients much less attractive financially[3] because of a new fixed per diem payment system authorized by the Balanced Budget Act of 1997 (BBA'97). IRFs continued to be paid on a cost basis and remained exempt from any prospective payment system until 2002. Thus, for seniors, choices for rehabilitation may be shaped by the extent to which HMOs reenter the Medicare market—a choice that may not always be transparent to individuals when they make their health plan choices during open enrollment periods.

Premium support demonstration

The premium support demonstration will have no immediate implications for Medicare beneficiaries, but it does portend what is to come. *Premium support* is simply a fancy term for private health insurance or private health plan and is a code word

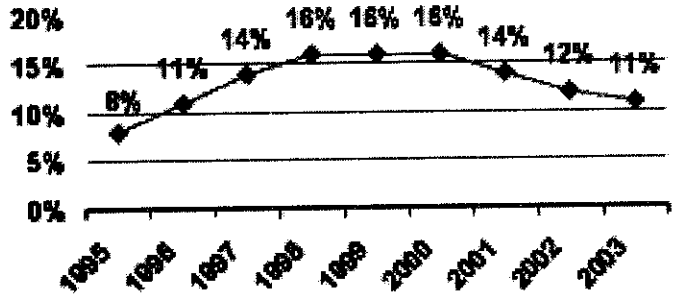

Figure 2. Medicare managed care enrollment.

for privatizing Medicare. In Congressional parlance, it means that private health plans could compete with traditional Medicare much like Medicare HMOs have done and that Medicare would provide beneficiaries a fixed payment with which beneficiaries would purchase their own private plan. In short, the Medicare program would become a defined contribution plan rather than a defined benefit plan. The implicit assumption in the premium support model is that Medicare is inherently inefficient and that if beneficiaries were offered a voucher of sorts with which to purchase their own health plan, traditional Medicare as we have known it would eventually wither away as market forces presumably favor private plans.

The premium support concept has been simmering in Republican think tanks and Congressional circles for a long time. In fact, Congressional Republicans did not want to offer a prescription drug plan unless the premium support concept came with it, because they knew that a premium support plan would not pass without the votes that a prescription drug benefit would garner if both were in the same package. In the end, Congressional Republicans only got half a loaf. Instead of a premium support program, they got a premium support demonstration that will not start until 2010 and will be limited to six markets. The demonstration authorization was a major disappointment to many Congressional Republicans who wanted a full-fledged premium support program, but the White House also wanted to have a prescription drug benefit to run on in the 2004 election.

Much could happen between now and 2010 when the demonstrations are rolled out. More important is the overall shift in the Medicare program that the premium support model portends. Congressional Republicans very much want Medicare to resemble the private health plan market. They also argue that the Medicare benefit package is outdated and is based too much on what health insurance plans looked like back in the 1960s, as in the case of Blue Cross/Blue Shield plans that included a Part A for hospitalization and Part B for outpatient services. Hence, the notion of Medicare "modernization" that one finds in the title of the MMA'03.

Health savings accounts (HSAs)

A favorite and recurring Republican concept is the idea of the health savings account (HSA), previously known as the medical savings account (MSA). This provision applies to all individuals, not just Medicare beneficiaries, and is not likely to be taken up by Medicare beneficiaries, given their cost and utilization profiles relative to the structure of the HSA outlined in the MMA'03. I mention them here because, like some of the other provisions, HSAs portend a larger shift in American health and social policy that I address later in this article. Discussing it here provides some of the empirical evidence for the larger argument that I want to make later.

An HSA is a tax-free health-related account analogous to individual retirement accounts (IRAs). Individuals, employers, or family members can make tax-free contributions to an account whose earnings and distributions remain tax-free. The HSA follows the individual and does not dissi-

pate when an individual leaves an employer, as does his or her group health insurance. It remains in perpetuity with the individual. The amount that can be put into an HSA is up to 100% of a deductible associated with a catastrophic health plan. Such health plans typically have upwards to a $5,000-deductible before the health plan begins to make outlays. The notion is that the individual is "self-insured" for the amount of the deductible, and, when responsible for the deductible, individual HSA participants will be more judicious consumers of health services and thus limit utilization and costs and slow the overall growth of health spending in the American economy. The minimum deductible under a qualified HSA is $1,000 for individual coverage and $2,000 for family coverage. Moreover, individuals 55–65 years old can make additional tax-free "catch-up" contributions of $1,000 analogous to the way near-retirement age individuals can make catch-up contributions to an IRA or to a 401(k) or 403(b) plan. Individuals and families can use their HSAs to pay for unreimbursed medical expenses, retiree health insurance, and other items not covered by their health plan. This presumes, of course, that a qualified medical expense under an HSA is broader than one defined by Medicare or a private health plan.

The downside to HSAs is the problem of adverse risk selection where younger and healthier persons are more prone to select an HSA and older and less healthy individuals are prone to select an alternative plan. The adverse risk selection problem can result in a downward spiral for conventional health plans as premiums become more expensive and healthier people opt out for other plans that feature HSAs with lower premiums. This is one of the reasons why MSAs and HSAs have not been embraced in the group health markets up till now and remain largely a feature of the individual and small business health insurance market.

The Devolution

Aside from its potential advantages or disadvantages, the larger message in HSAs as in other provisions of the MMA'03 is that the onus will shift to the individual to make informed choices and take more responsibility for health care expenditures. This is the defining feature in the other provisions as well—in the prescription drug benefit, the Medicare Advantage program, and the premium support concept. Some may look at the Medicare reform legislation and cast it into the traditional left–right debate about the role of the individual and government, with one side favoring greater individual responsibility and the role of markets and the other side favoring greater individual protections and the role of government. Casting the debate in these dichotomous terms may have some heuristic continuity with past debates about American social policy, but it masks other important trends in American life and economy that cannot be reduced to simple left–right dichotomies. My central thesis is that the MMA'03, as illustrated by the provisions outlined earlier, is part of a larger "devolution" of American life and economic behavior.

Devolution, as it is traditionally understood, refers to the transfer of power, authority, responsibility, duties, and accountability to a subsidiary entity or person. It is a term that is most commonly used to characterize the devolving of responsibility and accountability from higher levels of government to lower levels of government, from the federal government to state and local governments. The term is now widely used in the United Kingdom where there has been a vigorous debate about the extent to which government responsibilities previously anchored in London should be reallocated to the UK's constituent governments in Scotland, Wales, and Northern Ireland.

I am referring to devolution in its broader meaning, that is, the devolving of responsibilities, duties, tasks, and accountability to the individual citizen, the consumer, the beneficiary, the user, and the individual employee. I would argue that this is one of the defining features of our time, and yet it is not adequately recognized or understood, Thus, when applied to social policy, devolution risks creating mischief as well as new opportunities for individual empowerment.

The American devolution is perhaps most evident in the self-help economy that has emerged over the last 25 or more years as illustrated in **Tables 1** and **2**. Organizations are increasingly outsourcing their work to their customers and

Table 1. Examples of devolution in the American economy

Activity	Previously	Now or in the future
Pumping gas	Attendant	Driver/consumer
Checking in at airport	Ticket agent	Kiosk
Checking out at store	Cashier	Consumer check out
Banking	Teller	ATM
Computer trouble-shooting	Original vendor	Consumer or 800 number in India
Employer–employee transactions	Went to human resources dept; submitted travel reimbursement to administrative support staff	Enroll online for health benefits; manage travel reimbursement online using Oracle or PeopleSoft software

clients and "outsourcing" their administrative tasks to their employees. Many of the examples cited in **Tables 1** and **2** precede the rise of the Internet during the 1990s, but the Internet has become the facilitator, if not the great accelerator, of the American devolution. More important, I believe, is the way the devolution is spreading to the management of income and health benefits, both private and public.

On the income benefits side, employers have, over the last few decades, shifted from defined-benefit to defined-contribution retirement plans such as 401(k), 403(b), and cash-balance plans that place most of the burden on the individual to make investment choices. The choices involve not only asset allocation decisions between stocks and bonds (complex in themselves), but they also require extensive research with regard to third-party administrators (e.g., TIAA-CREF, AIG-VALIC, Fidelity Mutual), their fee structures, hidden insurance charges, withdrawal options, and tax implications. For the most part, employers have abdicated their role as honest information brokers and sometimes have conflicts of interests that are not transparent to employees. Some companies require that employees invest a significant portion of their 401(k) investments into the company itself—sometimes leading to disastrous results as in the case of the Enron scandal.

If the current Administration and Republican Congress prevail, Social Security will also shift from a strictly defined-benefit program to more of a defined-contribution plan as suggested by the proposals for individual private Social Security accounts. The transformation of portions of the Social Security program into a series of giant 401(k)- or 403(b)-like retirement programs will present individuals with enormously complex choices that are already difficult to make in the private sector.

On the health insurance side, employers are diversifying their offerings that allow employees to choose health plans that more nearly match their needs and health care consumption patterns. Increasingly, we hear about cafeteria plans and consumer-driven health plans that also come with donut holes, that is, plans that come with first-dollar coverage and deductibles around the mean annual health spending.[4] These plans are difficult for employees to evaluate because many employees cannot ascertain in advance their risk of reaching the donut hole. My more cynical side wonders whether donut-hole plans are merely another surreptitious method of risk selection that will attract consumers whose health care expenditures will remain well below the mean.

The devolution has now reached nearly every aspect of American life, including areas that may not be immediately apparent to those caught up in the devolution. At the workplace, for example, employers are shifting more of the administrative burden for human resource activities, time reporting, benefit management, travel and expense reimbursement, research grants management, and so on from support staff to line staff through the use of Internet or Intranet protocols made available from software vendors such as IBM, Oracle, and its

Table 2. Examples of devolution in American health and social policy

Program area	Previously	Now or in the future
Employer-sponsored retirement programs	Fixed employer pensions Defined-benefit programs	Cash balance plans & defined-contribution plans, e.g., 401(k), 403(b)
Government-sponsored retirement programs	Fixed pension Defined-benefit program Social Security as we have known it	Individual retirement accounts (IRAs) Individual Social Security Accounts akin to 401(k) and 403(b)
Employer-sponsored health benefits	Fixed benefit plan Defined coverages	Flexible spending accounts (FSAs) Consumer-directed health plans Health savings accounts (HSAs)
Government-sponsored health benefits, e.g., Medicare	Fixed benefit Fee-for-service (FFS) Medicare Medicare as we have known it	Medicare + Choice Medicare Advantage Premium support

recently absorbed rival, PeopleSoft. These protocols are expected to save organizations millions of dollars as whole layers of support staff are eliminated. This streamlining can be efficient but also enormously frustrating to individual employees who need to make transactions that do not conform to the protocols or transactions that are sufficiently infrequent and thus require the employees to relearn the protocol upon each application.

Organizations are similarly shifting more of the administrative burden for service dispute and account resolution to the individual or another member of the individual's family. Each time a consumer calls an 800 telephone number that triages the caller with a series of touch-tone options, the organization is essentially outsourcing an administrative burden from it to the caller. American companies have become leaner and meaner, but the presumed savings may also mean that costs are hidden on the consumer side of the equation and fail to get factored into most measures of economic activity and productivity. The reported productivity gains in the American economy in recent years may merely represent a shift in the cost of production from the supply side to the demand side of the market and may not represent any real productivity gain at all.

Embedded in the American devolution is tremendous lip service to the notions of consumer choice, consumer direction, and consumer empowerment—all terms used to legitimize public policy choices with respect to income and health benefits. But as neoclassical economic theory suggests, these terms have little meaning unless certain preconditions are met. For consumer choice to be meaningful, there has to be transparency and a means to compare apples with apples and oranges with oranges. In the economic theory of the perfectly competitive market, there must be a homogenous product, that is, meaningful comparisons should be made within a class of similar goods and services. In health care, this argues for a standard health-plan benefit package or groups of standardized packages as is currently present in the Medicare Medigap market where beneficiaries can choose from 1 of 10 different standardized plans and thus make genuine comparisons about price and scope of service. Apart from the Medigap market, this kind of standardization is not widespread in health care. When plans and offerings are not standardized, there is an even greater need for transparency and side-by-side comparisons with respect to benefits, costs, and fees that might otherwise be hidden from the consumer.

Equally important, consumers need honest and disinterested third-party brokers of information. Employers could do a lot more to be honest brokers of health plan information, although they are not always disinterested parties. In the case of Medicare, government has attempted to be an honest broker of information with the development of hotlines and beneficiary-oriented websites. CMS staff have made near-heroic efforts in rolling out the new prescription drug benefit to Medicare beneficiaries, but CMS's record in educating the public about an interim discount card for prescription

drugs has not been encouraging. A test of the Medicare hotline (800-Medicare) for discount prescription drug cards—run by a private contractor—found that 29% of callers received inaccurate information and another 10% received no information at all.[5] One can only imagine the confusion that is bound to follow as more choices become available in the Medicare program. The problem is neither CMS nor call center operators but a Congress that has created a nonstandardized benefit program with thousands of variables that even the best-educated and well-informed can never fully understand.

Government has already made some important strides in this area. For many years, the Agency for Health Care Research & Quality (AHRQ), the nation's lead health services research agency, has worked with its contractors and CMS to develop the CAHPS (Consumer Assessment of Health Plans) technology that enables consumers to compare health plans on the basis of subscriber satisfaction scores. MMA'03 also provides support for the Hospital Quality Initiative (HQI), a joint effort of American Hospital Association, the Federation of American Hospitals, and the Association of Academic Medical Centers (AAMC). At this stage of its development, the HQI remains limited to the development of 10 quality measures on only three sentinel health conditions: myocardial infarction, heart failure, and pneumonia.[6] As a financial incentive to participate, hospitals that participate in the HQI and meet all the reporting requirements will receive a full inflation-adjusted update in the amount in their payment schedule under Medicare and those that do not will receive 1.4% less. CMS has already developed analogous quality measures for nursing homes (10 quality measures) under the auspices of the Nursing Home Quality Initiative[7] and for home health agencies (11 quality measures) under the auspices of the Home Health Quality Initiative. CMS publishes these quality measures on its websites to enable beneficiaries and consumers to compare facilities and agencies in their home areas. Some of these measures, admittedly embryonic, are controversial and reflect some of the inherent limitations of administrative databases such as the minimum data set (MDS) for nursing homes and OASIS for home health agencies.

This kind of information can help beneficiaries make more informed choices about health plans and providers, but it does not address many other basic questions. Many of the questions center on how the changed Medicare program will interface with other income and health benefit programs. For example:

- If I have a Medigap policy with a drug benefit, should I enroll in the new Medicare prescription drug plan or would I be better off with a Medicare Advantage plan (Medicare HMO plan) that offers a drug benefit?
- If I am eligible to participate in a state-sponsored pharmacy assistance program, how will it affect my out-of-pocket expenses for the new Medicare prescription drug program?
- Will the new federal subsidy for company-sponsored retiree health benefits provide the level of drug benefit that is as good as the stand-alone Medicare benefit? If so, what are my risks if my former employer decides to discontinue the retiree health benefit as many employers are now doing? To what extent does my employer-sponsored health plan provide "wrap-around" coverage for my Medicare benefit?

These are not easy questions even for the best-informed and most-educated beneficiaries or soon-to-be beneficiairies. Only the Internet can provide an adequate platform for managing these kinds of choices. With or without the Internet, these choices presume that Medicare beneficiaries have the navigational skills to sort out the choices and make informed decisions. There remains a great generational divide that separates older Americans from many of their younger counterparts in knowing how to navigate the information that is already on the Web. For many older Americans, even the old QWERT keyboard—so essential to the navigation process—represents foreign and frustrating territory.

The American Association for Retired Persons (AARP) addresses many of these issues and underscores many of the challenges that seniors face as consumers and financial managers in the rapidly changing marketplace. A recently released report entitled *Beyond 50: A Report to the Nation on Consumers in the Marketplace* notes that consumers have less time to make more decisions, they face increasingly complex products and services, and they must do

so with low levels of financial literacy.[8] AARP makes three sweeping recommendations:

- Make product information, labeling, and disclosures easier to understand, more accurate, and useful;
- Increase the quality and integrity of advice to consumers; and
- Empower consumers with new tools and technology.

Overlooked in this discussion are the millions of younger and older Americans who lack the cognitive skills needed to process the information and make good choices. Each year, for example, there are 700,000 new stroke survivors, many of whom come away with diminished capacities for self-determination. We can add to this number the larger number of under-educated seniors and a subset of seniors who experience varying degrees of dementia and cognitive degradation in the final years of life.

The increasing complexity of choices presents a challenge for individual beneficiaries and their family members but also for providers who depend on third-party payment such as Medicare. Providers are going to have to learn much more about the benefit coverages that individual patients may or may not have and find ways to assist patients to arrange their financial affairs in a way that will help facilitate the services they need both in the short and long term.

What is essential in decision making is good client representation (which some family members are able to do well) and good and impartial information brokerage. Too much information brokerage is provided by those who have an interest in the outcome of the decision, for example, commission-paid financial advisors and health-plan representatives. Providers, though not disinterested, can do more. Steps in this direction, for example, are two publications from the National Rehabilitation Hospital: *A Consumer Guide for People with Stroke: Choosing a Rehabilitation Program*[9] *and Choosing a High Quality Medical Rehabilitation Program.*[10] These kinds of information brokerage can go a long way in helping to build a franchise with an organization's clientele.

Ultimately, we will have to turn to other organizations that have the impartiality, the command of the issues, and credibility to be honest brokers in the American devolution much like the Consumers' Union in the consumer market. Some organizations that come to mind include AARP, the Medicare Rights Center, and groups such as the National Academy of Social Insurance. Most important is government itself, either as a provider of information or as a facilitator and funder of information-dispensing organizations. To fulfill the promise of the American devolution, we must invest massively in the information infrastructure to make the devolution work effectively for both the sponsors and beneficiaries for both the supply and demand sides of the market. Transparency is essential to well-functioning markets and even more so in markets that are as complex as the future of Medicare portends.

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ORIGINAL ARTICLE

Opening the Black Box of Poststroke Rehabilitation: Stroke Rehabilitation Patients, Processes, and Outcomes

Gerben DeJong, PhD, Susan D. Horn, PhD, Brendan Conroy, MD, Diane Nichols, PT, NCS, Edward B. Healton, MD, MPH

ABSTRACT. DeJong G, Horn SD, Conroy B, Nichols D, Healton EB. Opening the black box of poststroke rehabilitation: stroke rehabilitation patients, processes, and outcomes. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S1-7.

This article introduces the journal's supplement devoted to the methods and findings of the 7-site Post-Stroke Rehabilitation Outcomes Project (PSROP), a study designed to provide a very granular in-depth understanding of stroke rehabilitation practice and how practice is related to outcomes. The article summarizes current knowledge about the effectiveness of post-stroke rehabilitation, outlines where the PSROP fits into the broader traditions of stroke rehabilitation outcomes research, underscores the study's methodologic innovations, and summarizes the scope of the articles that follow.

Key Words: Intervention studies; Rehabilitation; Stroke; Treatment outcome.

THIS *ARCHIVES* SUPPLEMENT reports on the Post-Stroke Rehabilitation Outcomes Project (PSROP), a large, multicenter stroke rehabilitation study that entailed the collaboration of 7 hospital-based rehabilitation centers—6 in the United States and 1 in New Zealand. These 7 centers enrolled nearly 1400 stroke rehabilitation patients from 2001 to 2003. The study's database (N=1291) provides an in-depth view of inpatient rehabilitation practice. This supplement reports on the motivation for the study, its methods, and findings across several dimensions of practice. This supplement also addresses important epistemologic issues in rehabilitation research that are raised by the methods and findings of the PSROP.

Stroke remains among the most compelling public health issues in the world today. In the United States alone, an estimated 700,000 people experience a new or recurrent stroke each year.[1] Approximately one quarter of these people die, and a significant portion of the remainder survive with long-term disability. There are approximately 4.8 million stroke survivors in the population, and about 1.1 million of these report having functional limitations. In economic terms, the estimated direct and indirect costs of stroke are $56.8 billion per year, as of 2005.[1,2]

Stroke survivors account for about 17% of all inpatient rehabilitation admissions. Although lengths of stay (LOSs) in rehabilitation settings have diminished considerably over the last few decades, rehabilitation remains an extended and labor-intensive affair that has seen few major breakthroughs. Much of what we do in stroke rehabilitation may be routine, but much also remains a trial-and-error matter that is difficult to characterize. Rehabilitation practitioners, it is said, customize their interventions to each individual patient. One result is that stroke rehabilitation practice varies from one patient to another and from one rehabilitation center to another and thus often lacks the standardization that is being demanded in other areas of medical practice, as evidenced by the development of practice guidelines and standardized protocols. In other words, stroke rehabilitation remains a "black box" of sorts. We have good ways of characterizing what goes into the black box (ie, the patient) and what comes out (ie, the patient) but little notion of how best to characterize what goes on inside the black box. Our failure to do so also limits our ability to know exactly what the active ingredients are in the rehabilitation process that are supposed to shape patient outcomes. This lack of specificity also limits the claims that providers and consumers can make of health plans and government to secure the financial resources needed for stroke rehabilitation.

CURRENT KNOWLEDGE OF THE EFFECTIVENESS OF POSTSTROKE REHABILITATION

Stroke survivors constitute one of the largest consumer groups of postacute rehabilitation services in the American health care system.[3] Among inpatient rehabilitation facilities (IRFs), industry data for 2004 indicate that the average Medicare reimbursement per day for a stroke survivor is about $1050 and that the average LOS is 17.3 days. In this age of continuous quality improvement, cost containment, reimbursement reduction, and the drive for evidence-based practice (EBP), rehabilitation providers are obligated to make sure what they are doing is clinically effective, cost efficient, and supported by data. Despite the large body of stroke rehabilitation research, the truth is that we do not know exactly how the $1050 per day is spent. Medicare and sundry health plans remain willing for the moment to provide the funding for stroke rehabilitation.

Of the more than 700,000 people who experience a stroke each year,[4] about 300,000 to 400,000 will need some rehabilitation services.[5] These stroke survivors will be assessed and given initial rehabilitation treatments while in acute care; will be screened by a representative of a rehabilitation facility, both for clinical need and financial support availability; and then will be transferred or discharged to one of any of the following: a free-standing rehabilitation hospital, a rehabilitation unit located in an acute care hospital, a skilled nursing facility (SNF) for subacute rehabilitation, a nursing home for residential ac-

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commodations and care, or to home for care by family and to receive rehabilitation services either at home or as an outpatient. If the survivor goes to a hospital-based rehabilitation center—now commonly referred to as an IRF, he/she will receive an ongoing therapeutic program that consists of round-the-clock rehabilitation nursing and physician coverage; daily physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP); and possibly additional services from psychology, social work, therapeutic recreation, vocational rehabilitation, and rehabilitation engineering staffs. In addition, stroke rehabilitation patients will have access to medical consultants of all possible types, specialist nurses such as those for skin and ostomy care, chaplains, family members, legal representatives, insurance company case managers, and research investigators and their assistants.

The interaction between each stroke survivor, his/her comorbidities, personal behaviors, and coping ability and all of these health care providers and family members is complex and highly specific—with each and all factors having a possible impact on a patient's outcome. The interaction of the patient with the facility's system of care comprises the process of care that heretofore has not been systematically disaggregated, measured, and evaluated to determine the most active ingredients that affect patient outcomes.

The following is a far-from-exhaustive review of some important research findings about stroke rehabilitation in IRFs. In 1982, Lind[6] reviewed the 7 best studies on the effectiveness of inpatient stroke rehabilitation. The results of these observational studies were conflicting and were only weakly comparable because of variations in research methods. Three studies showed a positive effect as a result of rehabilitation, 3 studies showed no effect, and the seventh showed a negative effect. Twenty years later (2003), Teasell et al[7] were unable to find substantially more depth or consistency in their review. They reviewed 272 randomized controlled trials (RCTs) but were unable to find even 2 RCTs confirming the efficacy of any particular treatment.[7] In 2002, Langhorne et al[8] observed that before the field of stroke rehabilitation can evolve into an evidence-based field of practice, the field must first establish a reliable evidence base. Ottenbacher and Jannell[9] noted that most RCTs in stroke rehabilitation are too small or scientifically inadequate to provide reliable guidance in establishing EBP.

Langhorne coordinated the Cochrane Stroke Unit Trialists' Collaboration (SUTC),[10] a meta-analysis of RCTs that compared dedicated stroke units with conventional care units in several European countries. The meta-analysis included 19 trials and concluded that stroke units have superior immediate and 1-year outcomes, in terms of function and survival. One would want to jump immediately into the data, to drill down and see what it was about the stroke units that produced the superior outcomes, but this level of data was not captured by any of the studies included. The best Langhorne could accomplish was to define stroke units as "geographically distinct wards with dedicated stroke teams, who provide coordinated multidisciplinary rehabilitation, programmes of education and training in stroke, and specialization of medical and nursing staff"[10]—and that is the extent of it.

Another problem of existing research on stroke rehabilitation is scientific rigor, with relatively few studies achieving what is commonly referred to as level 1 evidence. Moreover, the subject matter, selection criteria, measures used, and variables used in each study are sufficiently variable, making comparisons between studies difficult at best. The SUTC study supported the superior outcomes of stroke units[10]; Price and Pandyan's study[11] of poststroke shoulder pain supported the use of functional electric stimulation (FES). It cannot be known, however, whether the SUTC units used FES to improve their outcomes by reducing shoulder pain. This noncompatibility and lack of a comprehensive database compromises generalizability of results. Of course, not every study should be fully compatible with all others.

There has been substantial progress in the associated fields of neuroscience, radiology, medicine, and pharmacology to address the issues related to stroke management in recent years. Tissue plasminogen activator treatment protocols are gradually becoming the national standard of care for the initial presentation of an acute stroke at emergency departments.[12,13] Deep vein thrombosis prophylaxis is now routine and includes combinations of Doppler screening and the use of various antithrombotic drugs and compression devices.[14-16] Finding better methods to prevent initial and recurrent cerebrovascular accident remains an ongoing challenge for both the medical and research communities.[17-19]

In addition to published research, there are national databases that record various aspects of the inpatient rehabilitation stay. The Centers for Medicare and Medicaid Services (CMS), for example, requires that all IRFs acquire data on all their patients on admission and at discharge using the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI).[20] Moreover, accrediting agencies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and Commission on Accreditation of Rehabilitation Facilities require that IRFs acquire outcome data on patients. JCAHO, for example, under the auspices of its ORYX initiative, requires that IRFs capture data on LOS, FIM score change, and discharge destination for each patient.[21] IRFs report these data mainly to 1 of 2 national data systems—to eRehabData.com of the American Medical Rehabilitation Providers Association, an industry trade association, or to the Uniform Data System for Medical Rehabilitation. The upside to these databases is that they bring greater uniformity to the acquisition of rehabilitation patient data and aid in making comparisons across facilities. The downside is that they lack the depth needed to effectively examine stroke rehabilitation practice in any detail—nor would we expect these databases to do so. These data sets are limited mainly to patient data captured at admission and discharge, and nearly everything that happens in between remains largely unknown—the proverbial black box of rehabilitation.

A few studies have begun the process of opening and examining rehabilitation's black box.[22,23] The excellent recent article by Bode et al[24] was a multicenter study looking at IRF-PAI data, billing data, and discharge data but was limited to a sample of 177 patients—indicating once again how difficult it has been to penetrate the black box.

The neuroplasticity thesis has also spawned new research that examines the efficacy of specific interventions. For example, there has been substantial research evaluating the applications of the constraint-induced movement theories of Taub et al,[25,26] and modified versions of the initial protocol appear promising.[27,28] These newer interventions, however, rarely are compared with existing interventions or other therapeutic approaches such as neurodevelopmental therapy (NDT) or proprioceptive neuromuscular facilitation (PNF). They are usually considered in isolation from the large bolus of other rehabilitation-related interventions. Research on mental and physical practice, applications of learning theory,[29] task-specific training,[30] and functional imaging have all contributed important concepts to the treatment of patients with stroke in the clinic today. They allow us, for example, to see activation patterns of the brain to help understand motor recovery.[31-35] We hope that the knowledge gained will lead to the develop-

ment of new training approaches. Other new technologies being tested are the use of virtual reality and robotics to aid in the recovery of lost function.[36-46] However, the best practices of existing therapeutic approaches have yet to be ferreted out.

The spring 2003 issue of *Topics in Stroke Rehabilitation* contained several detailed evidence-based reviews on numerous outcome and efficacy studies in stroke rehabilitation. Studies were rated based on the number and quality of RCTs. For example, Teasell et al[7] developed a list of clinical findings based on RCTs having strong level 1 evidence. These findings, however, are quite nonspecific. They suggest that stroke rehabilitation improves functional outcomes, but it is not known whether the physical therapists used NDT, PNF, body weight–supported (BWS) gait training, FES, or had the patient practice walking. Did the occupational therapists use FES, slings, shoulder taping, positioning, tone inhibitory techniques, shoulder injections, or some combination of these to achieve the greater intensity of therapy to improve functional outcome? Did the treatment of neglect include placing all items of interest on a patient's left side, or were red markings placed on the left side of all objects, or was there simply "maximal cueing"? Did patients with greater functional improvements receive serotonin-specific reuptake inhibitor antidepressants, stimulants, atypical antipsychotic medications, combinations of these, or none of these? To date, research on current practice has been able to tell us little more than that "rehab is good." Now it is time to drill down, to get to the nitty-gritty of inpatient stroke rehabilitation. What really happens, how often, and to what effect?

These kinds of questions are not answered easily using traditional clinical research methods such as RCTs unless one is prepared to apply an RCT to each of these variations of practice—a solution that is neither practical nor likely to occur given current limitations in rehabilitation research funding. Clearly, different methods must be found if we are to address the various combinations and permutations of practice, including methods that provide highly granular-level data and allow researchers to examine microprocesses such as the impact of shoulder-hand syndrome pain and its treatments on participation and progress in rehabilitation. The clinical practice improvement (CPI) method used in the PSROP addresses this need for more granular treatment data, as outlined in the next section.

The 1995 Agency for Health Care Policy and Research (AHCPR) Post-Stroke Rehabilitation Guideline on stroke rehabilitation provided a review[47] of the best research available at the time and supplemented that review with expert consensus recommendations in those instances where the literature did not provide level 1 evidence. The guideline panel found very few level 1 studies. Eight years later, in 2003, the Veterans Health Administration (VHA) issued its own stroke rehabilitation guideline[48] by significantly updating the work of the 1995 AHCPR guideline, taking into account the studies conducted in the intervening years. The PSROP database offers a rare opportunity to test the AHCPR and VHA guidelines by determining whether patients treated in keeping with the guidelines had better outcomes. A previous study of 288 stroke survivors at 11 VHA sites throughout the nation found that compliance with AHCPR guidelines was positively associated with outcomes.[49-51] Because this study was conducted within the VHA, it remains uncertain whether the findings generalize to women stroke survivors as well as men. The chief limitation in using the guidelines developed to date as a point of departure for future research is their lack of specificity, which mirrors the underlying literature's lack of specificity with regard to the exact nature and timing of rehabilitation therapies such as OT and PT, including their intensity, frequency, and duration—the very dimensions captured by the PSROP.

THE PSROP

The PSROP began initially as one of several projects under the auspices of the Rehabilitation Research and Training Center on Measuring Rehabilitation Outcomes hosted at Boston University's Sargent College and funded by the National Institute for Disability and Rehabilitation Research in 1999. The leadership team for the study was drawn from 2 organizations: the Institute for Clinical Outcomes Research in Salt Lake City, UT, and the National Rehabilitation Hospital's (NRH's) Center for Health and Disability Research in Washington, DC. As the scope of the PSROP increased, additional funding was provided by the NRH Neuroscience Center with a grant from the U.S. Army and Materiel Command. The National Blue Cross Blue Shield Association contributed to the acquisition of 6-month follow-up data from the NRH site. Various authors who contributed to this supplement did so under the auspices of their own funding sources in addition to those mentioned here.

The PSROP's Principal Research Question

The PSROP's main research question is an enduring one: what impact does each stroke rehabilitation activity or intervention, both individually and collectively, have on patient outcomes on discharge, controlling for patient differences including medical and functional status on admission? This rather global question can be partitioned into a series of subsidiary questions, several of which are addressed to one degree or another in the articles represented in this supplement. Answering these questions required the acquisition of detailed in-depth data on patient characteristics, processes of care, and outcomes and the creation of a large relational database that is described more fully in Gassaway et al.[52]

Critical to the success of the PSROP has been the steadfast participation of the study's 7 clinical sites in the design, data collection, and analysis phases of the project. The 7 sites participated vigorously and contributed far beyond the funding levels provided by the project. The 7 sites and their respective site directors are identified by Gassaway.[52] The participation of front-line clinicians was especially important to the study's attempts to characterize rehabilitation activities and to collect data documenting each stroke rehabilitation activity and intervention.

We distinguish between activity and intervention, a distinction underscored by the PSROP's clinical contributors. An activity, to borrow examples from PT, might include bed mobility, sitting, gait or walking, and community mobility. An intervention, to use PT again, may include strength exercises, aerobic or conditioning exercises, electric stimulation, parallel bars, BWS gait training, and family education, to cite only a few of the 57 interventions coded in the study. At the risk of some oversimplification, there are 2 broad levels at which individual therapies can be analyzed: the activity level and intervention level (ie, the therapy intervention used to facilitate each therapy activity). This supplement is limited largely to the therapy activity level and not to the intervention level. We seek first to determine how participation in individual activities—in terms of timing, duration, frequency, and intensity—shape outcome. In subsequent work we want to determine how interventions within select activities shape outcomes.

The PSROP's Methodologic Innovations in Rehabilitation Research

We devote an entire supplement to the PSROP because of its scope and depth but also because it breaks new ground in

rehabilitation research methods. One breakthrough has been the PSROP's approach to characterizing the black box of stroke rehabilitation. To do so, it was first necessary to develop a taxonomy of stroke rehabilitation activities and interventions. It was never the intent of the PSROP to develop a stroke rehabilitation activity or intervention taxonomy, but investigators and collaborating clinicians determined that they could not go further if they did not have a working taxonomy of activities and interventions that used a common vocabulary and uniform methods of documenting stroke rehabilitation activities and interventions. The de facto taxonomy that evolved from the study has been outlined previously by DeJong et al.[22] We do not present this taxonomy as a definitive one for stroke rehabilitation but believe that it serves as a working taxonomy that provides useful insights into how future and more formal stroke rehabilitation taxonomies might be developed.

The PSROP is a CPI-type of study that is essentially an observational cohort study with 3 added features. First, CPI studies systematically harness the collective wisdom of frontline practicing clinicians and use their insights in planning the study, defining the treatments to be evaluated, narrowing the hypotheses to be tested, developing the data collection instruments, and collecting and analyzing the data. Second, to control for patient differences, CPI studies capture the clinical complexity of each patient by using the Comprehensive Severity Index in addition to measuring functional status, a mainstay of rehabilitation studies. Third, CPI studies use detailed descriptors of rehabilitation processes made possible by the taxonomy of rehabilitation activities and interventions, as noted. Like many observational studies, CPI studies use multivariate analyses to identify the variables most associated with outcomes, but CPI's distinguishing features, particularly the detailed characterization of activities and interventions, allow researchers to unravel relations that might not otherwise become apparent. A full-fledged CPI study includes a fourth feature: it ascertains the predictive validity of the findings by evaluating the outcomes that result when study findings are introduced into practice as part of a larger practice improvement strategy, a feature that also gives this genre of study its name—clinical practice improvement. The PSROP did not include this fourth feature.

A CPI study's methodologic features also address some of the weaknesses found in RCTs. For more on the relative advantages of CPI and RCT studies, the reader is directed to a commentary by Horn et al.[53]

A central theme in clinical and health services research is the call for EBP, a call that is sometimes synonymous with a call for more RCTs in health care, including rehabilitation. Unfortunately, there may never be enough resources or time to address all the myriad forms of rehabilitation practice through randomized trials. There are no good shortcuts in rehabilitation research, but we do have to find a faster way of ascertaining what constitutes EBP in rehabilitation. Current methods for determining best practices are much too slow and too expensive. A strength of the CPI approach is its ability to uncover best practices more quickly than conventional methods, and such practices can later be vetted in validation studies or through controlled trials. A major challenge is knowing what therapeutic activities and interventions are truly ready for prime-time controlled studies. In the earnest quest for randomized studies, we risk wasting rehabilitation research resources on studies that may show no or minimal differences. Through the use of CPI-type studies, many promising therapeutic activities and interventions can be identified and unproductive activities and interventions weeded out in advance of such confirmatory studies.

The PSROP's Limitations

Every study has its limitations, and this study is no exception. First, the PSROP did not include data beyond discharge into the postrehabilitation period, except at 2 sites that had made independent efforts to follow up patients up to 6 months after their strokes. Hence, the PSROP can provide insight into the more immediate effects of stroke rehabilitation therapy but not into its long-term effects. The original level of funding simply did not permit the research team to probe beyond the rehabilitation episode, except in the 2 instances already noted.

Second, the study's documentations of nursing activities and interventions are not as strong as those for the mainline rehabilitation therapies. The study was conducted during a period of serious nurse shortages that, in some instances, compromised the completeness of the nursing data, and thus these data are not reported in this supplement.

Third, as an observational cohort study, the PSROP focuses on the associations between various rehabilitation inputs and outcomes, not on causation of outcome. Nonetheless, as seen in subsequent articles, some findings and themes remain remarkably consistent across different patient subsets and therapy activities.

Fourth, there are other real or perceived limitations—for example, potential selection bias and other classic study limitations—although 1 hallmark of this study has been its ability to control for patient differences through the use of a detailed severity-of-illness adjuster that probes well beyond similar tools. These and other limitations are addressed in the supplement's other articles.

Finally, the study's unit of analysis was very much at the patient level and did not address major differences such as organizational milieu and interdisciplinary team coherence—although team conferences were considered a rehabilitation activity or intervention. The long-standing work by Strasser et al[54] on rehabilitation team functioning has shown positive associations between various dimensions of teamness with patient outcomes. One could make the case that well-functioning teams result in better outcomes, because they organize care more efficiently at the patient level. They may also have an independent effect on outcomes because team culture may spill over onto therapist and patient mood and behaviors that affect the rigor of their participation. The PSROP did not capture this dimension of the rehabilitation experience.

Some Findings

The PSROP offers several insights into the stroke rehabilitation process as we know it today. We want to share an insight or 2 that transcend the individual articles represented in this supplement.

An important finding is the large practice variations between facilities represented in the study. For example, we find enormous variations in the use of medications such as antidepressants, with no clear clinical indications for the observed variations. We rarely think of medication as a distinct rehabilitation intervention in the same way we think of the 3 therapies most closely identified with rehabilitation—namely, OT, PT, and SLP. Moreover, the management of affective disorders can greatly affect a patient's ability to participate in these therapies. There is much room to identify best, or at least better, practice in this area.

The PSROP also examines the relative distribution of therapy activities within and between the 3 main rehabilitation therapies. PSROP investigators are struck, for example, by how little attention is given to community mobility and integration activities relative to other therapy activities. Future studies will

need to determine how the neglect of these areas affects longer-term outcomes. Such studies are needed to inform providers, health plans, and other payers about the relative merits of these activities in fostering greater community independence and mobility after discharge.

One of the more compelling insights to emerge from the PSROP and the articles presented here is that earlier and more aggressive therapy is better, controlling for patient differences. In other words, starting therapy earlier is better than later, and moving patients on to higher-order and more difficult activities more quickly has a way of resolving some of the lower-order activities that rehabilitation providers sometimes focus on as necessary steps to more advanced activities. The earlier-is-better observation confirms many previous studies. The more-aggressive-is-better finding presents new opportunities to improve practice and presents new hypotheses for research. The case for the earlier-and-more-aggressive finding is also evident in some of the differential findings between the United States and New Zealand facilities. Compared with New Zealand facilities, U.S. facilities provide a more aggressive shorter-term program of rehabilitation with better outcomes, despite a more challenging case mix.

SCOPE AND ORGANIZATION OF THE SUPPLEMENT

This supplement consists of 11 articles and 1 commentary, plus 2 commentaries by third parties. The second piece in this series is a commentary that raises fundamental epistemologic issues in rehabilitation research and identifies the methodologic genre of research from which the PSROP springs. In short, it provides the methodologic context that also enables the reader to understand better the contributions and limitations of the PSROP.

The third article[52] serves as the common methods piece and baseline findings for the articles that follow. We chose to provide a separate baseline article describing the study's methods and the study group's principal characteristics because of the PSROP's nontraditional approach and because the baseline article reduces the need for each subsequent article to repeat all the same background material with respect to study design and study group characteristics. Instead, each subsequent article's methods section summarizes the study's overall methods and focuses on those methods that are more specific to the topic of the article, especially if subsets of the study group were used and not the entire study group. We encourage readers of subsequent articles to have a basic acquaintance with this baseline article to more fully interpret the findings of individual articles that follow and to understand the limitations of the study. We also encourage readers to become acquainted with an earlier article[22] published by the study team on stroke rehabilitation intervention taxonomies, as noted earlier.

A long-standing issue in rehabilitation is the timing of rehabilitation—timing from onset of the stroke and timing from acute hospital care to rehabilitation. The conventional wisdom has been that early rehabilitation results in better outcomes and that undue delays from acute care to rehabilitation result in further deconditioning and atrophy that limit participation in therapy or require a more prolonged rehabilitation process. The supplement's fourth article examines this question and confirms much of the conventional wisdom on this topic.

The supplement's fifth, sixth, and seventh articles examine and characterize the content of inpatient rehabilitation's 3 main therapies—PT, OT, and SLP. Previous studies have been able to quantify the hours or minutes of therapy received over the course of an inpatient rehabilitation stay, but they provide little insight into the actual content of the 3 therapies with respect to specific activities and interventions and how much of each therapy activity or intervention was associated with higher levels of function and independence. The authors examine how participation in select therapy activities relates to progress in specific functional activities (eg, gait training, walking).

The authors of the 3 therapy articles do not attempt to show how participation in select activities relates to overall functional status at discharge and discharge disposition. This discussion is reserved for the supplement's 11th article, in which we bring all the independent variables together in explaining the study's observed outcomes. One of the lessons learned is that there is overlap of activities across the 3 therapies and that looking at these activities within the confines of the individual therapies in isolation from the other therapies provides an incomplete picture of the therapeutic encounter. The take-home message from this experience is that we cannot examine rehabilitation practice and therapy merely through the lens of individual therapy professions but need to look across professional domains to understand more fully how individual therapy activities and interventions relate to functional outcomes.

In addition to rehabilitation's 3 core therapies, there are many other rehabilitation activities and interventions that the PSROP examined. We can report on only a few of these in this supplement. The supplement's eighth article examines the use of neurotropic drug therapy. Many patients with stroke experience poststroke depression or other affective disorders that may slow their recovery, limit their participation in therapy, and diminish their outcomes. The authors believe that drug therapy is an understudied area of stroke rehabilitation that is ripe for more significant advances in rehabilitation practice and outcome.

Similar observations could be made about the role of nutrition in stroke rehabilitation outlined in the supplement's ninth article. Many patients with stroke come to rehabilitation malnourished or inadequately hydrated either because of long-standing behaviors or because their new impairment may limit their ability to consume a more balanced diet. Nutrition is not commonly thought of as a rehabilitation intervention, but malnourished patients may lack the energy and mental focus needed to participate more effectively in rehabilitation therapy. In this area as well, we have observed considerable variation in practice and believe that a better understanding of the role of nutrition and malnutrition may help accelerate the rehabilitation process.

Midway through the PSROP, CMS implemented the long-awaited prospective payment system (PPS) for IRFs. The IRF-PPS presents important financial incentives that are likely to reshape provider behavior and rehabilitation practice. We believe that we cannot ignore this development and, coming midway through the PSROP data collection process in 2002, we have a singular opportunity to examine how the IRF-PPS may have altered the mix of stroke rehabilitation patients, the extent of therapy rendered, and the LOS. The supplement's 10th article provides a before-and-after–PPS view of stroke rehabilitation in 3 of the 6 U.S. facilities that had significant numbers in both the pre- and post-PPS periods. This article, however, did not find striking short-term changes in stroke rehabilitation practice, as had been expected.

The supplement's 11th article considers all the findings of the previous articles to help identify likely predictors of rehabilitation outcome in terms of functional status on discharge and discharge disposition. We chose not to examine these outcomes in previous articles except tangentially, in part because we believe that all patient and process variables cannot be evaluated independently of one another. Moreover, as noted earlier, the overlap in therapies across professional domains

requires an integrated analysis that simply cannot be achieved by looking at the impact of therapies in isolation from one another.

The PSROP's seventh site, the Wellington and Kenepuru hospitals in Wellington, NZ, provides an international dimension to stroke rehabilitation practice. The supplement's 12th article examines how stroke rehabilitation practice in New Zealand is both similar to, and different from, stroke rehabilitation in the United States as represented by the 6 U.S. sites. We added New Zealand to the original U.S. cohort in the interest of locating additional variation in practice that might not be available in the United States. (The original PSROP study design included SNFs as well as IRFs. In 2000 and 2001, when the PSROP got underway, the SNF industry was experiencing considerable turmoil in the wake of changes resulting from the Balanced Budget Act of 1997, and surviving SNFs were difficult to recruit.) Unlike RCTs, which require very rigid adherence to practice protocols, CPI studies like the PSROP thrive on practice variation to help differentiate intervention effects that might otherwise be more difficult to identify when there are fewer practice differences.

Although the New Zealand site is the only non-U.S. site in the study, the PSROP is very similar to a 4-country, 5-site study on stroke rehabilitation currently underway in Europe, known as the Collaborative Evaluation of Rehabilitation in Stroke across Europe (CERISE). Sponsored by the European Commission, the study is being led by a team of investigators in Belgium at the Free University of Brussels and the Catholic University at Leuven. CERISE and PSROP investigators currently are examining ways to merge their 2 databases to provide a richer cross-national understanding of stroke rehabilitation practice and outcomes and to achieve a level of understanding that cannot be achieved by the 2 databases independently. Moreover, because the CERISE study ascertained 6-month outcomes, merging these 2 data sets will enable researchers to make more effective use of the 6-month outcome data obtained from 2 of the PSROP sites—one in the United States and the other in New Zealand.

CONCLUSIONS

Given the depth and scope of the PSROP database, there is a great deal more to be explored than is represented in this supplement. The research and findings presented here offer insights as to how we can understand practice variation and find best practices in stroke rehabilitation. The search for EBP begins with a better understanding of current practice. All too often, the quest for innovation ignores the gems that already exist in current practice and within the collective wisdom of rehabilitation practitioners. The PSROP offers 1 way in which these gems can be identified and disseminated into mainstream stroke rehabilitation practice.

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COMMENTARY

Another Look at Observational Studies in Rehabilitation Research: Going Beyond the Holy Grail of the Randomized Controlled Trial

Susan D. Horn, PhD, Gerben DeJong, PhD, David K. Ryser, MD, Peter J. Veazie, PhD, Jeffrey Teraoka, MD

ABSTRACT. Horn SD, DeJong G, Ryser DK, Veazie PJ, Teraoka J. Another look at observational studies in rehabilitation research: going beyond the holy grail of the randomized controlled trial. Arch Phys Med Rehabil 2005;86(12 Suppl 2): S8-15.

This commentary compares randomized controlled trials (RCTs) and clinical practice improvement (CPI) approaches to study design, evaluates their relative advantages and disadvantages, and discusses their implications for rehabilitation research and evidence-based practice. Many argue that observational cohort studies are not sufficient as scientific evidence for practice change. We challenge this assertion by introducing the concept of a CPI study: a comprehensive observational paradigm structured to decrease biases generally associated with observational research. One strength of CPI studies is their attention to defining and characterizing the "black box" of clinical practice. CPI studies require demanding data collection, but by using bivariate and multivariate associations among patient characteristics, process steps, and outcomes, they can uncover best practices more quickly while achieving many of the presumed advantages of RCTs.

Key Words: Cerebrovascular accident; Clinical practice variations; Rehabilitation; Treatment outcomes.

A RECURRING CRITICISM in medical rehabilitation is the lack of adequate high-level research evidence with which to establish evidence-based practice. This criticism is not unique to rehabilitation and is echoed throughout the health care system. Tunis et al write,

> The current clinical research enterprise in the U.S. is not consistently producing an adequate supply of information to meet the needs of clinical and health policy decision makers . . . [due to] a systematic problem in the production of clinical research. . . . A consistent finding of [systematic literature] reviews is that the quality of evidence available to answer the critical questions identified by experts is suboptimal. . . . These gaps in evidence undermine efforts to improve the scientific basis of health care decisions. . . . [such that] clinical practice guidelines may not be able to develop clear, specific recommendations. [Typical] observational and other non-experimental methods may not provide sufficiently robust information regarding the comparative effectiveness of alternative clinical interventions, primarily because of their high susceptibility to selection bias and confounding variables.[1(p1625-6)]

Tunis calls for new research methods to meet these gaps. Berguer[2] discusses problems with the evidence in evidence-based medicine (EBM). The main tools of EBM are randomized trials and meta-analysis, but Berguer believes that these methods are unlikely to lead to the discovery of new and best treatments for specific types of patients. "[Rigorous] observational and inductive clinical intelligence should be stimulated and published because a therapy needs to be invented before it is proven effective. Biomathematicians need to improve nonrandomized methodology as they did for randomized studies."[2(p265)] To paraphrase Berguer, randomized controlled trials (RCTs) are important to the confirmation of new and/or current interventions and practices, not to the discovery of more effective and efficient interventions and practices.

There are additional calls for new approaches to EBM and performance in quality and costs of the health care system. Porter and Teisberg write, "The U.S. health care system has registered unsatisfactory performance in both costs and quality over many years."[3(p64)] They observe that medical services are restricted or rationed, many patients receive poor care, and high rates of preventable medical errors persist. There are wide and inexplicable differences in costs and quality among providers and across geographic areas. In well-functioning competitive markets, Porter and Teisberg argue, such outcomes would be inconceivable; in health care these results are intolerable. Competition in health care is operating at the wrong level: payers, health plans, providers, physicians, and others in the system wrangle over the wrong things. "System participants divide value instead of increasing it."[3(p65)] This form of zero-sum competition must be replaced by competition at the level of preventing, diagnosing, and treating individual conditions and diseases and determining the best treatments for specific types of patients. Encouraging competition at the level of treatments for specific diseases or co-occurring conditions and types of patients will speed the development of the right kind of information and improve value (quality of health outcomes per dollar expended). Value should be measured and improved at the disease and treatment level.[3]

Tunis's call for developing the next phase in the evolution of clinical trials is, namely, pragmatic or practical clinical trials

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(PCTs), for which the hypothesis and study design are developed specifically to answer the questions faced by decision makers in practice or as payers. "Characteristic features of PCTs are (1) select clinically relevant alternative interventions to compare, (2) include a diverse population of study participants, (3) recruit participants from heterogeneous practice settings, and (4) collect data on a broad range of health outcomes."[1(p1624)] "PCTs address practical questions about the risks, benefits, and costs of an intervention as they would occur in routine clinical practice"[1(p1626)] and address questions such as the following: Does the treatment work in the real world of everyday practice? For whom does the intervention work best? The PCT approach contrasts with explanatory clinical trials or efficacy studies (RCTs), which are concerned with questions such as the following: Does the investigational treatment cause an effect? How and why does the intervention work? Explanatory trials are designed to maximize the chance that some effect of a new or existing treatment will be revealed by the study. They are a form of confirmatory analysis where relations have been vetted already in previous research.

This commentary presents the clinical practice improvement (CPI) research method as a variant of the PCT called for by Tunis. As a clinical research method, CPI embraces all 4 elements of PCTs outlined above and, thus, is one way in which the PCT concept can be operationalized effectively.[4] The purpose of this commentary is to juxtapose RCT and CPI research methods by evaluating their relative strengths and weaknesses. We argue that PCT methods such as CPI can liberate us from the straightjacket that has constrained rehabilitation's ability to discover and establish standards for best practice.

RCTs: FEATURES AND CHALLENGES

The intellectual origins of RCTs come from agriculture. In agricultural hothouses, the environment can be reasonably controlled and various interventions tested. The RCT represents a research paradigm that had its origins in a simpler time when we did not have powerful multivariate statistical tools, and even when we had them, we lacked the computational power that readily accessible computer-based statistical packages have brought us over the last 30 years. As a research model, the RCT allowed one to make relatively simple computations using fairly small sample sizes; it was well suited to the computational constraints of an earlier era. RCTs do not harness the full power of multivariate statistics, in which many variables can be considered simultaneously and covariates can be identified and neutralized to evaluate intervention effects.

A hallmark of an RCT is the random assignment of study participants into a treatment arm and a control arm to neutralize participant differences that might otherwise affect the outcome. By neutralizing participant differences through randomization, RCTs help isolate the effect of the treatment under review. Nonrandomized comparison groups present the risk that some nontreatment effects remain unaccounted for and thus compromise one's ability to have full confidence that the outcomes are truly a consequence of the treatment or intervention under study.

When designed and conducted properly, RCTs are considered the criterion standard for establishing causality in scientific research. Clinical and health services research communities have come to accept hierarchies of evidence where RCTs are considered the highest level of evidence and anything less than RCT-level evidence is considered somewhat suspect. Using RCTs in rehabilitation presents several major challenges that are not easily overcome. We mention a few of them here and later discuss how a CPI approach is not bound by many of the same constraints.

Standardization and Artificiality

RCTs require that one use standardized treatment protocols and that one hold all other variables constant to isolate the effects of the intervention and to reduce noise in the data. One result is that the intervention setting can become artificial and may not reflect what would otherwise transpire under less-controlled circumstances in a real-world clinical environment. Standardized treatment protocols require extensive quality control to decrease error rates about the treatment. Treatment purity is difficult to maintain over time, across centers, and across clinicians; if compromised, an intention-to-treat analysis—which keeps everyone in the study and in their assigned groups even if the treatment protocol or control is not followed as prescribed—may be the best remaining analysis option. Unfortunately, intention-to-treat analyses no longer reflect efficacy.

Selection Criteria, Patient Recruitment, and Generalizability

Selection criteria for participation in a study are often quite restrictive to reduce variation stemming from differences among study participants. Restrictive selection criteria limit the generalizability of a study's findings (external validity) to the types of people represented in the study. The study's findings may not apply to the types of people excluded from the study. For example, many studies exclude people with comorbidities, although significant comorbidities are common in many rehabilitation populations and may affect or alter outcomes. Clinicians may be prone to dismiss RCT findings, because they deem their patients to be quite different from those seen in a clinical trial. Restrictive selection criteria can also result in studies with very small numbers, drawn from a much larger pool of otherwise eligible participants. Typically, only a small percentage of patients—usually 10% to 15%—are eligible for a trial. Enormous resources must then be expended to recruit large pools of potential participants to locate people who meet the selection criteria and thus achieve the sample sizes needed to power the analyses.

Blinding

RCTs assume some degree of blinding. Ideally, all 3 actors—the study participant, the clinician, and the researcher or observer—are unaware as to whether the participant is in the treatment or control arm. Double blinding means that 2 of the 3 are blinded—both the participant and 1 of the other 2 actors—lest their knowledge about participant assignment affect their level of effort, their outlook, and the participant's willingness to continue with the nontreatment arm of the study. Rehabilitation interventions, including sham interventions, are not easily disguised and, in many cases, are impossible to disguise.

RCTs present other challenges, including ethical challenges to randomization and lengthy planning and approval processes that can sabotage even the best-designed studies. Most formidable is cost: an RCT can be very expensive, even prohibitively expensive, because it may require an elaborate protocol to screen patients, coordinate care, and collect data. For example, the Medical Outcomes Study and the Health Insurance Experiment conducted by Rand in the 1980s cost sponsor organizations more than $35 million and over $60 million in 2005 dollars. Other large RCTs of practice effects cost about the same.

All of this leaves rehabilitation in a real bind. On one hand, rehabilitation practice needs the validation that sound scientific evidence can provide. On the other hand, its highly customized multifactorial approach does not lend itself well to RCTs, which require a more limited set of interventions and selection criteria that can make participant recruitment difficult and expensive and make study findings less generalizable. We quickly could exhaust a good portion of the world's entire biomedical research budget in a given year to study all the rehabilitation interventions and combinations of interventions used around the world. Over the years, many variants of the RCT have evolved to address 1 or more of the challenges identified but cannot overcome limitations that are inherent in an RCT.

OBSERVATIONAL DATA AND CAUSAL INFERENCES

It is generally accepted that a decision is unwarranted if the supporting evidence is based on accidental associations. Confidence in an action depends on confidence that the supporting evidence implies a causal connection. As mentioned above, randomization underlying the RCT provides a relatively high degree of confidence in this regard, but the resulting evidence can be costly to obtain, not germane to the relevant clinical context, and easily compromised by small deviations from the design. An alternative is to use data with a naturalistic genesis representing the population and circumstances of interest. In such data, however, subjects are not randomized into the various treatment groups; consequently, analyses often cannot discern whether differences in outcomes are due to different treatments or to other differences between subject groups.

This problem has generated considerable effort to create methods that identify treatment effects using observational data. Since the last quarter of the twentieth century, a large literature has developed on causal inferences and observational data.[5-11] Methods have been created that allow for unbiased estimates of treatment effects by controlling for unmeasured confounders.[8,11] Unfortunately, these methods cannot identify all treatment effects of interest and are often sensitive to assumptions that are not testable. Also, they require considerable knowledge in statistics to understand and adjust sufficiently for nuisances, making them less useful to researchers and less understandable to decision-makers who do not have the requisite statistical background.

Alternatively, methods that sidestep the issue of unobserved confounding have been developed as well. Specifically, the method of instrumental variables allows for estimation of treatment effects in the presence of otherwise unobserved confounding.[12] However, the treatment effect is instrument-specific and may not be of interest. In addition, it can be difficult to identify and measure the required variables, and—similar to the preceding methods—the necessary assumptions are not testable. As another alternative, the observed data can be analyzed as if there are no unmeasured confounders and then subjected to a sensitivity analysis of potential confounding.[7] To be useful, however, this approach requires assumptions regarding the unknown confounding, and little is gained if results are determined to be sensitive to assumptions.

With enough data, if all factors influencing the distribution of both the interventions of interest and the outcomes of interest are measured and controlled for in analysis, then treatment effects can be identified from observational data without the need for sophisticated statistical models and untestable assumptions. Unfortunately, when confounding factors are not controlled statistically, the treatment effect may not be distinguishable from spurious correlations. It has been shown that under some circumstances controlling for only a subset of confounders can generate greater bias than controlling for none.[13-15] Heckman and Navarro-Lozano[13] provide a formal development of the point. Intuition suggests that if a set of factors have counterbalancing correlations with the outcomes and treatments (ie, some positive and some negative), then controlling for a select few can throw off the balance and generate greater bias.

Because in real-world settings it is not likely that all confounders can be identified and measured, a researcher is faced with 3 options: (1) pursue a costly RCT that may not address the clinical context of interest, (2) embark on statistically sophisticated methods that trade one set of untestable assumptions (ie, the identification of all confounders) for another set of untestable assumptions (the necessary distributional or correlation assumptions underlying selection and instrumental variable models), or (3) report an analysis that does not account for confounding, mention the deficit as a limitation, and let the user beware.

However, if the goal is to produce useful information and reduce uncertainty for decision-makers, the situation may not be so constrained. We suggest a paradigm shift toward the pragmatic. As stated at the beginning of this section, it is generally accepted that the decision to pursue a course of action is unwarranted if based on evidence of an accidental association; consequently, structuring research to minimize the potential for accidental association will improve its usefulness.

Rather than focus on meeting conditions for statistically unbiased causal effect estimates, we propose designing observational studies that focus on minimizing the plausibility of alternative explanations while estimating the complex associations between treatments and outcomes within a specific context of care. The identified associations are not equated with causal parameters but nonetheless inform such judgments to the extent that the design minimizes alternative explanations. This is a process-oriented approach: the goal is to structure the design carefully to capture the salient information bearing on the research question. The proposed design trades uncertainty regarding generalizability in the case of the RCT, or uncertainty in necessary assumptions underlying the statistical methods mentioned above, for uncertainty regarding the potential for alternative explanations while explicitly minimizing the plausibility of such explanations. Also, the proposed CPI method is available for use by most researchers with access to the standard computational power of today's personal computers and a knowledge of basic multiple regression techniques.

CPI: FEATURES AND CHALLENGES

CPI harnesses the complexity presented by patient and treatment differences, offering a naturalistic view of treatment by examining what actually happens in the care process.[4] It does not alter the treatment regimen to evaluate the efficacy of a particular intervention as one does in an RCT. The CPI approach offers the advantage of large numbers of patients—numbers that often cannot be attained in an RCT constrained by stringent selection criteria.

CPI is an observational study design whose measurement encompasses a comprehensive view of the care management process: (1) key patient characteristics, (2) all treatment and care processes, and (3) outcomes. All 3 classes of data are considered simultaneously (fig 1). This comprehensive measurement framework provides a basis for meaningful analyses of significant associations between process and outcome, controlling for patient differences.

CPI designs include detailed measures of patient factors (physiologic severity of illness and psychosocial abnormalities

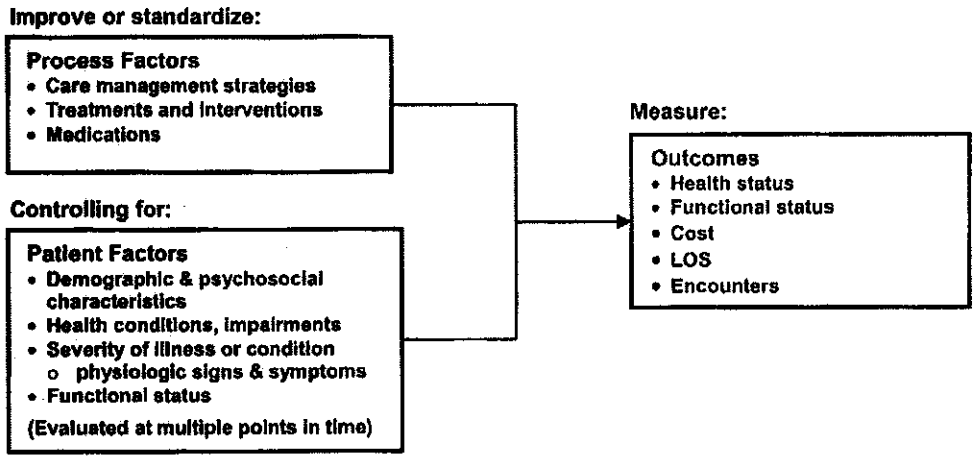

Fig 1. Three essential components for a CPI study. Abbreviation: LOS, length of stay.

presented at each visit or each admission), care process factors (eg, medications, treatments, interventions), and outcome factors. It presents the resulting associations to clinicians, so they can evaluate objectively the effects of the treatments they give to similar patients. Without all 3 types of data (eg, if one has only process and outcome data, but not detailed patient data), clinicians cannot tell if the outcomes achieved are due to the process steps or to differences in patients' illness severity levels.

Patient Factors

Patient factors are the key characteristics of the study population: demographic characteristics, specific indications for treatment, severity of illness, initial functional status, psychosocial factors, and others. A CPI design addresses a central feature in RCT design—namely, the need for randomization to neutralize the effect of patient differences. Randomization is used when patient differences cannot be taken into account adequately. On the other hand, CPI studies incorporate detailed information about patients and their needs and account for these differences through statistical analyses to control for patient differences. Detailed patient profile data include condition-specific physiologic data, such as those contained in the Comprehensive Severity Index (CSI).[4,16-21] The CSI is described in detail in the article[22] outlining the study's methods and is a unique severity-of-illness measure used in CPI studies.

Care Process Factors

A process of care is a sequence of linked, usually sequential, steps designed to cause a set of desired outcomes to occur. The goal is to find a measurable factor that describes each major process step. Examples include which drugs are dispensed, what dose is used, and what rehabilitation therapies are performed and for how long. A data collection instrument records the process steps in detail, including timing and dates. Thus, CPI studies require that clinicians and researchers characterize fully and accurately the actual interventions used. The level of detail about processes and interventions contained in CPI studies is unique.

Outcome Factors

Processes of care are designed to achieve specific outcomes. Among the outcomes commonly assessed are condition-specific complications, condition-specific long-term medical outcomes (based on clinician assessment or patient self-report), patient functional status, patient participation in society, patient satisfaction, and cost. Outcome factors may be thought of as analogs to the assessment endpoints in an RCT.

To capture all of these factors, CPI studies entail the creation of a large study database that includes all the patient, process, and outcome variables of interest. Multivariate statistical methods are then used to compare alternative treatments while controlling for other variables that may be driving observed differences between treatments and outcomes. These statistical methods allow the researcher to examine relations far more complex than those using only 1 explanatory or treatment variable at a time. The coefficients of the significant independent variables in regression equations identify key process steps that, when controlling for patient factors, are associated with better outcomes.

The CPI focuses on application—that is, on actionable findings that can be implemented to improve the process of care and treatment outcomes. The focus on implementation also governs who is involved in the study design, what data are collected, what questions are answered during analyses, and who designs the protocols or improvements in routine practice. Thus, CPI studies place a premium on the participation of clinicians in the study design, study execution, analyses of data, and implementation of study findings. Those actually providing the care are involved in all phases of the project, and their involvement also facilitates the buy-in needed to implement the findings and the care improvement processes.

RCT AND CPI STUDIES COMPARED

Table 1 compares RCT and CPI studies across several dimensions. We argue that CPI-like observational studies can help overcome some of the limitations that are inherent in RCTs. The conventional wisdom, however, is that RCT studies provide superior evidence relative to observational studies, yet there is growing empirical evidence that supports the use of well-designed observational studies akin to CPI studies relative to RCTs to discover what works best in medicine. Two studies[23,24] found that treatment effects from observational studies and RCTs were remarkably similar. Both studies concluded that they found little evidence that estimates of treatment effects in well-designed observational studies were either consistently larger than or qualitatively different from those obtained in RCTs. A third article found the same thing: comparing results on 45 topics with binary outcomes there was "very good correlation ... between summary odds ratios of randomized and non-randomized studies

$r=0.75$, $P<.001$ for all studies,

$r=0.83$, $P<.001$ for prospective studies."[25(p821)]

Table 1: RCT and CPI Studies Compared

Variables	RCT	CPI
Patient variables	Patient eligibility and stratification factors	Patient eligibility and stratification factors
	Eliminate patients who could bias results: comorbidities, more serious disease, etc	Use severity of illness to measure comorbidities and disease severity
	About 10%–15% of patients qualify	All patients qualify by measuring patient differences; none excluded
Process variables	Treatment protocol	Measure or record all treatments and interventions
	Specify explicitly every important element of the process of care for both treatment and control arms	Abstract information from charts based on existing practice
	Informed consent	Informed consent often not needed*
Outcome variables	Powered for primary outcome	Many outcomes assessed
	Change based on evidence	Improvement based on evidence
Measurements/ documentation	Limited number of patient variables, treatments, outcomes measured	Comprehensive holistic framework
	Variables specified precisely for all patient, treatment, and outcome measures	Variables specified precisely for all patient, treatment, and outcome measures
Database	Limited to the variables needed	Comprehensive and detailed
Result	Efficacy	Effectiveness
	Assigned causality	Association and assumed causality
Hypotheses	Typically 1 hypothesis	Typically many hypotheses
	Clearly defined at the start	Many and broad at the start
	Narrow and focused	Refined and new hypotheses generated by analytic findings
Local knowledge	Not dependent on local knowledge	Depends on local knowledge; entails participation by practicing clinicians
Confounders	Assumed not relevant to study or outcome	Affect outcomes and are relevant to include

*Informed consent may not be required if there is no experimental intervention and if there are no data collected beyond what is ascertained from medical records and from reports prepared by clinician in the course of usual care.

These studies concluded that well-designed observational studies do not systematically overestimate the magnitude of the effects of treatment as compared with those in RCTs on the same topic. In addition, "the popular belief that only RCTs produce trustworthy results and that all observational studies are misleading does a disservice to patient care, clinical investigation, and the education of health care professionals."[24(p1892)]

CPI has the ability to identify important associations in many diagnostic groups. Table 2 gives examples of CPI studies and selected treatments that were associated with better patient outcomes, their positive impacts on patients, and their positive impacts on health care systems (eg, reduced length of stay and/or costs).[26-37]

DISCUSSION

A key advantage of a CPI study is the naturalistic view of medical treatment that is provided by retrospective data recorded routinely by medical providers. This view is critical to determine implications of treatment alternatives. In everyday practice, patients are assigned to different treatments based on the provider's medical judgment, patient compliance is not artificially influenced, and monitoring of results is based on the provider's need for information about how a patient is doing. All these factors can affect the effectiveness of medical treatment. CPI analyses help the team evaluate current practices and use the results to develop evidence-based improvements. Changes to the process of care rest on clinical data rather than on clinical opinion.

This approach directly contrasts the approach of traditional RCTs. Because their participants are screened, selected, and subjected to scrutiny and intervention control beyond that occurring in everyday treatment, RCTs sometimes report results that are not broadly applicable in everyday medical treatment. For example, a recent study described a little-used 40-year-old drug, spironolactone, which was shown in a landmark clinical trial in 1999 to significantly reduce death and hospitalization for patients with congestive heart failure.[38] There was a 4-fold jump over 18 months in prescriptions for the generic drug. That surge in use was accompanied by a tripling of hospital admissions and of deaths resulting from dangerous elevations of potassium. Many patients given the medicine likely would have been excluded from participating in the original clinical trial. The researchers noted that the new findings offer a provocative look at the difference between clinical trials and real-world medicine—and the potential dangers of applying trial results too widely. Patients in clinical studies typically are selected carefully to maximize the chance of showing a benefit and minimize side effects. Thus, trial patients represent only a subset of the types of patients doctors treat in their offices. Patients given the medicine in the aftermath of the 1999 study were on average 13 years older than participants in the original trial and were more likely to have diabetes. Also, the average dose in actual practice was 30mg, whereas 25mg was used in the study.[38] CPI studies can provide evidence to determine those medications and interventions that work best for specific types of patients in real-world practice.

Another key advantage of CPI study methods is cost. Using existing data from medical records and computerized databases is generally much less costly than implementing a prospective RCT. Using retrospective data allows for a much larger number

Table 2: Examples of CPI Studies, Selected Findings, and Their Effects

CPI Project	Selected Significant Findings	Associations	Implications
Abdominal surgery[32]	Early feeding (start within 48h after surgery) Sufficient feeding (>60% of protein and calorie needs)	Shorter LOS Lower hospital cost	Even though they had higher average severity of illness, patients fed early and sufficiently had between 1.4 and 2.9 days shorter average LOS and between $1940 and $5281 lower average cost per case than patients fed either not early and/or not sufficiently
Abdominal surgery[29]	Use of PCA pump	Higher rate of postoperative surgical wound infection	10.7% infections for PCA users vs 4.0% for non-PCA users
National Pressure Ulcer Long-Term Care Study[31]	Disposable briefs Supplement use Combination medications	Fewer pressure ulcers	Less suffering and lower cost to treat in nursing homes
Formulary limitations in the elderly[35]	Greater formulary limitations	Higher health care resource utilization—more doctor office visits, more ED visits, and more hospitalizations per year	Common cost-containment strategies are associated with higher health care resource utilization
Asthma drugs[36]	Use of newer asthma drugs	Lower overall drug costs and fewer PCP visits per year	Common cost-containment strategies are associated with higher health care resource utilization
Diabetes study[37]	Self-monitoring of blood glucose along with consistent provider discussion	Better serum glucose control and fewer hospitalizations	Monitoring alone is not sufficient; discussion of results with providers is essential
Infants hospitalized with RSV[30]	33–35wk gestational age infants hospitalized with RSV	Higher intubation and longer ICU and hospital LOS	Consider prophylaxis for 33–35wk gestational age infants

Abbreviations: ED, emergency department; ICU, intensive care unit; LOS, length of stay; PCA, patient-controlled analgesia; PCP, primary care provider; RSV, respiratory syncytial virus.

of observations that can be available for analysis and for further hypothesis generation and refinement.

Observational studies do not scientifically prove the causality of any underlying relations, but they can point to hypotheses that can be evaluated clinically. There are 3 ways to ascertain causality from CPI studies: (1) no added confounders cause the significant association to disappear, (2) a change in outcome follows a change in treatment as predicted by the CPI model,[4] and (3) repeated studies on the same topic yield the same findings. In short, CPI studies have shown predictive validity because observations show that outcomes change as predicted when practices are changed to those associated with better outcomes in the CPI analyses.

An RCT cannot always be conducted in rehabilitation medicine when sufficient evidence of treatment efficacy does not exist to justify one, projected sample sizes are small, or the question cannot be studied with an RCT (eg, what is the role of psychologic disturbances in outcomes). However, safeguards and protections built around RCTs (other than randomization) can be used in research methodologies such as observational studies, thereby increasing the level of evidence provided by studies using research designs other than RCTs. CPI does this by developing a comprehensive database of patient, treatment, and outcomes variables.

Instead of being viewed as competitive or mutually exclusive, RCTs and CPI should be considered complementary. Practice effects of RCTs can be tested in CPI studies, and CPI can be a progenitor of new RCTs.

Today, data needed to conduct a CPI study typically are abstracted by hand from existing paper medical records or documented prospectively on standardized forms. In the future, hospitals will use computerized clinical information systems (CISs). Then, rather than relying on labor-intensive manual data abstraction, needed patient, process, and outcome data can be found electronically in hospitals' CISs. The efficiency and logistics of this new data acquisition modality will make it easier and less costly to conduct iterative CPI studies to determine best practices. Also, the resulting research-based protocols can be programmed into a hospital's CIS to alert clinicians to the most appropriate protocols or interventions needed to address specific combinations of patient signs and symptoms. This should result in more consistent implementation of clinical practice guidelines and the protocols suggested by such guidelines.

CPI studies constitute a rigorous form of quasi-experimental research. Although they are weaker than RCTs on internal validity, they are stronger on external validity. CPI studies better represent actual conditions of practice, and they usually cost less and take less time. Because they do not insist on homogeneous patient populations, they allow the inclusion of patients with comorbidities or complications. To avoid confounding the link between the interventions and outcomes, they measure relevant

patient characteristics using severity assessment tools and statistically adjust for differences in patients. Further, they accommodate departures from rigid treatment protocols by carefully monitoring and measuring actual treatments; they then use these data in statistical analysis. Because this approach does not disqualify large numbers of patients, it facilitates the generation of the number of cases needed for comparisons. Using multiple regression and other statistical techniques, researchers test process steps that are associated with the quality and cost outcomes sought for different kinds of patients.

Although CPI studies tend to focus on short-term outcomes, these outcomes include effects that are noticeable and holistically important to patients rather than only those that are physiologically measurable through laboratory or other tests. CPI studies are designed to be replicated easily so they can be undertaken at multiple sites.

In a commentary on alternatives to RCTs for traumatic brain injury rehabilitation, Whyte states, "It appears nearly impossible to successfully apply observational designs when the factors leading to the applications of different treatments are strongly related to the patient's perceived prognosis."[39(p1320)] CPI adjusts for this by using condition-specific, physiologic-based measures of severity such as the CSI and other control variables.

CONCLUSIONS

The most appropriate design for a specific study depends on the nature of the research question and the type of knowledge that is needed. Methodology alternatives such as CPI do not replace RCTs, but rather provide additional sources of systematic outcomes information that improve on the anecdotal and informal knowledge base that underlies much of clinical practice. CPI studies used by clinical teams have enormous power to enable health care providers, managed care organizations, payers, and patients to evaluate current practice and improve clinical decision making. These studies answer questions in the real world, where multiple variables and factors can affect the outcomes.

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ORIGINAL ARTICLE

Applying the Clinical Practice Improvement Approach to Stroke Rehabilitation: Methods Used and Baseline Results

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ABSTRACT. Gassaway J, Horn SD, DeJong G, Smout RJ, Clark C, James R. Applying the clinical practice improvement approach to stroke rehabilitation: methods used and baseline results. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S16-33.

Objectives: To describe the methods used and baseline data for the Post-Stroke Rehabilitation Outcomes Project (PSROP).

Design: Prospective observational cohort study.

Setting: Seven inpatient rehabilitation facilities (IRFs) in the United States and New Zealand.

Participants: Consecutive convenience sample of 1291 poststroke rehabilitation patients, age older than 18, who were treated between 2001 and 2003 in 7 IRFs (1161 patients in 6 U.S. IRFs).

Interventions: Not applicable.

Main Outcome Measures: Change in FIM score, change in severity of illness, and discharge destination.

Results: For the U.S. sample, the average age was 66 years, 52% were men, 60% were white, and 23% were black. Medicare was the most frequent payer. Seventy-seven percent of strokes were ischemic, with 43% in the left brain, 44% in the right brain, and 11% bilateral. Mean admission total FIM score was 61, with a mean motor FIM score of 40 and mean cognitive FIM score of 21. Lower FIM scores are associated with higher severity-of-illness scores. Mean rehabilitation length of stay was 18.6 days; 78% of patients were discharged home. At discharge, the average increase in total FIM score was 26, in motor FIM score was 22, and in cognitive FIM score was 4.

Conclusions: This article outlines methods used in the PSROP, provides an overview of participating IRFs, describes the database, and summarizes key characteristics to enable readers of subsequent articles to better interpret study findings and determine generalizability.

Key Words: Outcome assessment (health care); Rehabilitation; Severity of illness index; Stroke.

THE TERM *BLACK BOX* has been used to describe specific components (interventions) of the stroke rehabilitation process, because specific details about activities used throughout the course of rehabilitation are lacking in rehabilitation literature.[1-6] Stroke rehabilitation practices are customized to meet individual patient needs, which results in variation from one patient to another and from one rehabilitation center to another. Standardized protocols that exist in other areas of medical practice are not common in stroke rehabilitation, which accounts for about 20% of all inpatient rehabilitation admissions. A rationale for the study and detailed literature review substantiating the need to examine rehabilitation processes to improve outcomes for specific types of patients is presented elsewhere.[7]

This article provides an overview of the methods used in a large multisite study of stroke rehabilitation outcomes known as the Post-Stroke Rehabilitation Outcomes Project (PSROP). It was a component of the Rehabilitation Research and Training Center on Medical Rehabilitation Outcomes commissioned by the National Institute on Disability and Rehabilitation Research. The PSROP addressed priority 2: the need for scientific data supporting the effectiveness of rehabilitation treatments for poststroke patients. The article also provides a characterization of the study group, the scope of care received, and an introduction to rehabilitation outcomes realized. It sets the stage for articles that follow, in which the PSROP's findings are reported.

The PSROP introduces to rehabilitation research a genre of research methodology known as clinical practice improvement (CPI).[8] CPI's fit into the pantheon of biomedical and clinical research methodology is described elsewhere.[9] A CPI study is an observational cohort study that entails the acquisition of prospective and retrospective data while not disrupting the natural milieu of treatment. CPI examines what actually happens in the care process and contains several distinct features, some of which are meant to compensate for the shortcomings commonly attributed to observational studies, particularly the ability to account for patient covariates. Because of CPI's methodologic complexity, a significant portion of this article is devoted to how CPI concepts were operationalized in the PSROP.

In the context of rehabilitation, the purpose of a CPI study is to discern the relative contributions of specific interventions and therapies to rehabilitation outcomes taking into account patient differences and other contributing factors. On 1 level, CPI studies are straightforward. They resemble other observational studies that take into account demographic-type patient and setting characteristics that may shape outcomes and determine generalizability. CPI then moves to a level beyond traditional observational approaches to create comprehensive, complex databases that include detailed patient-specific descriptions, severity-of-illness measures, and characterizations of rehabilitation treatments for large samples of patients. Moreover, CPI studies entail extensive clinical staff participation in all phases of study design, data collection, and analyses.

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Table 1: PSROP Participating IRFs

IRF	Location	Site Director	Facility Type	Bed Size
National Rehabilitation Hospital	Washington, DC	B. Conroy, MD	Freestanding	128
University of Pennsylvania Medical Center	Philadelphia, PA	R. Zorowitz, MD	Rehab unit	24
LDS Hospital	Salt Lake City, UT	D. Ryser, MD	Rehab unit	26
Legacy Health System	Portland, OR	F. Wong, MD	Rehab unit	33
Stanford University Hospital	Palo Alto, CA	J. Teraoka, MD	Rehab unit	17
Loma Linda University Medical Center	Loma Linda, CA	M. Brandstater, MD	Rehab unit	40 adult
Wellington & Kenepuru Hospitals	Wellington, NZ	H. McNaughton, MD	Rehab unit	25, 20

Rehab, rehabilitation.

METHODS

Overview

The CPI methodology was central to our approach in the PSROP because it captures in-depth, comprehensive information about patient characteristics (including clinical signs and symptoms), rehabilitation processes of care, and rehabilitation outcomes needed to characterize the process of care and ascertain the contribution of individual rehabilitation processes to outcomes. At the risk of some over simplification, there are 7 components to CPI methodology; the PSROP included the first 5 components, and the sixth and seventh components (validation of findings, incorporation of study findings into care protocols) will be the subject of future work. Each component is described briefly, followed by in-depth descriptions of the first 5 as related to the PSROP:

1. Create a multisite, multidisciplinary project clinical team whose tasks are to (a) identify outcomes of interest, (b) identify individual components of the care process, (c) create a common intervention vocabulary and dictionary, (d) identify key patient characteristics and risk factors, (e) propose hypotheses for testing, and (f) participate in analyses. The multidisciplinary project clinical team builds on theoretic understanding, research evidence to date, existing guidelines, and clinical experience about factors that may influence outcomes.
2. Use the Comprehensive Severity Index (CSI) to control for differences in patient severity of illness, including comorbidities that might otherwise affect outcomes. The CSI is an age- and disease-specific measure of physiologic and psychosocial complexity comprising over 2200 signs, symptoms, and physical findings.
3. Implement an intensive data collection protocol that captures data on patient characteristics, care processes, and outcomes drawn from medical records and study-specific data collection instruments. Data collectors are tested for interrater reliability.
4. Create a study database suitable for statistical analyses.
5. Successively test hypotheses based on questions that motivated the study originally, previous studies, existing guidelines, and, above all, hypotheses proposed by the project clinical team using bivariate and multivariate analyses including multiple regression, analysis of variance (ANOVA), logistic regression, hierarchic models, and other methods consistent with measurement properties of key variables.
6. Validate study findings via an implementation phase that tests the predictive validity of the findings. In this sixth phase, findings from the first 5 steps are implemented and evaluated to determine whether the new or modified interventions replicate results identified in earlier phases.
7. Incorporate validated study findings into standard practice of care. After the validation of specific CPI findings, the findings are ready to be incorporated into care protocols.

As noted, the PSROP did not include the validation implementation or protocol incorporation phases (6 or 7), which will be the subject of future work.

The CPI approach offers a naturalistic view of rehabilitation treatment by examining what actually happens in the care process. It does not alter the treatment regimen to evaluate efficacy of a particular intervention. Moreover, CPI's detailed data on rehabilitation interventions allow researchers to penetrate to the most meaningful level of resolution regarding the types of care rendered—consistent with current knowledge and insights offered by team participants. Thus, the CPI approach can answer study questions and hypotheses initially at a fairly basic level of resolution but also allows researchers to drill down into the data with the help of additional insights offered by clinical team participants.

PSROP Project Clinical Team

The project clinical team provided expert advice to ensure clinical meaningfulness to PSROP activities and analyses. It began as a core group consisting of the medical director from each of 7 participating inpatient rehabilitation facilities (IRFs). This core clinical team developed and implemented patient selection criteria, provided expert advice for data collection instrument development, obtained institutional review board (IRB) approvals at their respective affiliated university or research organization, oversaw the data collection process, and participated in analyses. Over time and depending on project activities/needs, the PSROP clinical team (hereafter "the team") expanded to include representatives of each discipline in stroke rehabilitation. Physical, occupational, speech and language, and recreation therapists; social workers; nurses; and psychologists provided expert advice specific to their fields of expertise. No clinicians or patients received monetary reimbursement for participation. Team members participated in weekly conference calls over much of the 5-year project and specialized subgroups teleconferenced as needed. Frequent team meetings contributed to overall collaboration and investment in the study's processes and findings.

PSROP Facilities

Table 1 lists the 7 (6 in the United States, 1 in New Zealand) IRFs that participated in the PSROP. IRFs were selected based on their willingness to participate and geographic location only. There were no specific criteria for selection, and thus, they are not a probability sample of IRFs in the United States. All facilities are nonprofit. One facility is free-standing; all others are rehabilitation units within an acute care setting. We

Table 2: Stroke CMGs and CMG Groupings by Relative Tier Weights

Stroke CMG Groupings	PSROP* Patients, n (%)	CMG	Stroke CMG Definition			Relative Weights			
			Motor FIM Score	Cognitive FIM Score	Age (y)	Tier 1	Tier 2	Tier 3	None
Mild (CMG 101–103)	148 (11.5)	0101	69–84	23–35	NA	0.478	0.428	0.408	0.386
		0102	59–68	23–35	NA	0.651	0.583	0.555	0.526
		0103	59–84	5–22	NA	0.830	0.743	0.708	0.670
Moderate (CMG 104–107)	511 (39.6)	0104	53–58	NA	NA	0.901	0.807	0.769	0.728
		0105	47–52	NA	NA	1.134	1.016	0.968	0.916
		0106	42–46	NA	NA	1.395	1.249	1.191	1.127
		0107	39–41	NA	NA	1.616	1.447	1.379	1.305
Severe (CMG 108–114)	548 (42.6)	0108	34–38	NA	≥83	1.748	1.565	1.492	1.412
		0109	34–38	NA	<83	1.890	1.693	1.613	1.527
		0110	12–33	NA	≥89	2.028	1.816	1.730	1.638
		0111	27–33	NA	82–88	2.089	1.871	1.783	1.687
		0112	12–26	NA	82–88	2.478	2.220	2.115	2.002
		0113	27–33	NA	<82	2.238	2.004	1.910	1.807
		0114	12–26	NA	<82	2.730	2.445	2.330	2.205

Source: Centers for Medicare and Medicaid Services.[32]
Abbreviation: NA, not applicable (CMG calculation rules for cognitive FIM score apply only to CMG 101–103 and for age apply only to CMG 108–114).
*6.5% PSROP patients have incomplete FIM information.

did not examine facility-specific patient admission criteria for participating IRFs. Each site contributed detailed data for about 200 consecutive poststroke patients for a total of 1291 patients (1161 patients in the United States). The inclusion of 1 international site (New Zealand) provides somewhat different approaches to rehabilitation care and our data confirm these differences. Thus, we elected to report results from New Zealand as compared with the U.S. sample in a separate article.[10] Apart from this article, the remaining articles in this supplement include only the 1161 U.S. patients, and therefore, this article describes information for U.S. patients only.

Each IRF enrolled consecutively admitted patients with stroke who met inclusion criteria; 5 sites began enrolling patients with stroke in March 2001; 2 sites began in June 2001. Facility size and rate of stroke patient admissions determined the duration of the enrollment period. Some sites enrolled 200 poststroke patients in about 8 months; other sites took up to 2 years. No eligible patients were excluded. Patients with stroke from these 6 U.S. IRFs constitute a convenience sample.

Subsequent articles will use specific subsets of the full PSROP database depending on the topic of each article. When subsets are used they are described fully and reasons for inclusion and exclusion of specific patients are provided.

PSROP Patient Selection Criteria

Each participating IRF obtained IRB approval for this observational study and enrolled consecutively admitted patients who met the following inclusion criteria:

(1) Rehabilitation diagnosis of 430 to 438.99, 997.02, or 852 to 853: one of these diagnosis codes was present in the list of *International Classification of Diseases, 9th Revision* (ICD-9),[11] codes in the rehabilitation record.
(2) Age greater than 18 years.
(3) First rehabilitation admission after current stroke, with the principal reason for admission being stroke. The patient may have had previous strokes and previous rehabilitation admissions for previous stroke(s), but this is the first admission for the current stroke. Current stroke must have occurred within 1 year of this rehabilitation admission.
(4) If a patient was transferred to another setting of care (eg, acute care hospital) and returned to the IRF within 30 days, the patient remained a study patient. If a patient transferred to another setting of care and returned to the IRF after 30 days, participation in the study ended on the day of transfer.

There were no exclusion criteria that might otherwise limit the generalizability of findings. Because the study did not entail a new or experimental intervention for which patient consent was needed, there were no refusals or study dropouts and, therefore, no need to compare study participants with study dropouts or need to account for patient selection effects that might otherwise occur. The study obtained informed consent from patients at only 2 sites (1 in the United States, 1 in New Zealand) for their participation in the collection of 6-month postdischarge outcomes at these 2 sites (6-mo outcomes were not collected at the other 5 sites and are not included in this or other articles in this supplement).

We also compared the PSROP study group to a national reference group of stroke patients (*http://eRehabData.com*) to understand better how similar or different PSROP patients are from those who might be found in other IRFs in the nation and to better determine the generalizability of PSROP findings. eRehabData is a subscriber-paid database maintained by the American Medical Rehabilitation Providers Association to monitor national trends and help estimate the programmatic and fiscal impact of federal policy on rehabilitation providers. We used national data only from 2002, mainly because eRehabData was not aggregated across the entire 2001–2003 study, and with only 1 year to choose from, we chose 2002—the midyear of the study period. About 180 rehabilitation providers contributed data to eRehabData for 2002. This is about 15% of all IRFs, but because eRehabData tends to attract larger facilities, its sample of patients is about 20% of the nation's IRF patients.

Data Collection

Three types of study data were obtained from multiple sources either at the point of care or from postdischarge chart review in the IRF: (1) patient characteristics (eg, admission

Table 3: PSROP Patient Characteristics

Characteristics	Site 1 (n=209)	Site 2 (n=198)	Site 3 (n=186)	Site 4 (n=199)	Site 5 (n=206)	Site 6 (n=163)	Site Variation Significance (*P*)	Full Sample (n=1161)	National Data*
Demographic and health plan characteristics									
Mean age (y)	68.0	67.5	65.7	64.4	66.1	64.2	.059†	66.0	69.7
Sex (% male)	49.8	56.1	51.1	58.3	47.6	47.9	.175‡	51.8	46.4
Race (%)							<.001‡		
White	29.2	68.2	50.0	85.9	82.0	27.6		60.6	ND
Black	61.7	7.1	12.9	7.5	1.0	71.2		23.2	ND
Other, including Hispanic	9.1	24.7	37.1	6.6	17.0	1.2		16.2	ND
Payer (%)							<.001‡		
Medicare	56.0	61.1	66.7	50.8	53.4	47.2		56.0	ND
Medicaid	6.7	0.0	15.6	12.1	3.4	23.9		9.7	ND
Commercial	36.8	38.4	9.1	36.2	32.0	28.2		30.5	ND
Self-pay	0.5	0.5	5.9	0.0	7.8	0.6		2.6	ND
Unknown/missing	0.0	0.0	2.7	1.0	3.4	0.0		1.2	ND
Health and functional status characteristics									
Stroke risk factors (%)									
Previous stroke (excludes TIA)	29.2	27.3	32.8	24.6	28.6	24.5	.485‡	27.9	ND
Hypertension diagnosis	82.3	74.6	75.3	75.4	81.1	82.8	.138†	78.6	ND
Diabetes diagnosis	37.8	23.2	32.8	24.6	32.5	33.7	.010†	30.8	ND
Obesity diagnosis	4.8	3.0	4.8	6.0	12.1	1.8	<.001‡	5.6	ND
Smoking history (%)							<.001‡		
Never smoked	53.1	52.0	16.1	43.2	60.7	44.8		45.5	ND
Quit >1y before stroke	21.0	25.3	12.4	25.6	17.5	17.2		20.0	ND
Current smoker	19.1	13.6	23.7	23.0	18.9	33.7		21.6	ND
Unknown/missing	5.3	8.6	47.9	7.5	2.9	4.3		12.5	ND
Type of stroke (%)							<.001‡		
Hemorrhagic	9.1	28.8	42.5	19.1	9.1	26.2		23.2	ND
Ischemic	90.9	71.2	57.5	90.9	80.9	73.8		76.7	ND
Side of stroke (%)							<.001‡		
Right	36.8	46.5	48.9	49.3	39.3	45.4		44.2	42.1§
Left	37.8	43.4	45.7	41.7	44.2	42.3		42.5	42.3§
Bilateral	22.5	7.6	3.8	8.0	12.6	6.8		10.5	3.0§
Unknown	2.9	2.5	1.6	1.0	3.9	5.5		2.8	ND
Location of stroke (%)							<.001‡		
Brainstem/cerebellum	19.1	20.2	11.8	18.6	18.0	23.3		18.4	ND
Subcortical	42.6	31.3	37.6	27.6	31.6	39.9		35.0	ND
Brainstem + subcortical	10.1	2.5	4.3	4.0	5.3	1.8		4.8	ND
Lobar	25.4	38.4	40.3	41.7	42.7	33.1		37.0	ND
Unknown	2.9	7.6	5.9	8.0	2.4	1.8		4.8	ND
Mean admission total FIM score	61.1	64.9	47.4	70.9	54.5	67.9	<.001†	61.0	56.7§
Mean admission motor FIM score	38.3	42.2	31.4	46.7	38.3	43.7	<.001†	40.1	35.5§
Mean admission cognitive FIM score	22.9	22.7	16.1	24.3	16.5	24.0	<.001†	21.0	ND
CMG (%)									
Mild (101–103)	4.3	10.1	3.2	16.1	13.1	8.6	<.001‡	11.5	ND
Moderate (104–107)	35.4	46.5	25.8	57.8	29.1	59.5	<.001‡	39.6	ND
Severe (108–114)	40.7	39.9	67.7	25.1	50.5	28.2	<.001‡	42.5	ND
Mean admission CSI score	19.5	12.8	27.0	15.3	30.0	19.7	<.001†	20.7	ND
Mean no. of diagnosis codes	11.3	10.3	12.8	7.9	15.4	6.0	<.001†	10.8	ND
Stroke symptoms									
Aphasia	19.6	24.2	39.8	18.1	16.5	12.3	<.001‡	21.8	ND
Complete hemiplegia	0.5	0.0	17.7	4.0	15.1	19.0	<.001‡	9.0	ND
Incomplete hemiplegia	91.4	98.0	62.4	86.4	56.8	65.0	<.001‡	77.2	ND
Dysarthria	51.7	41.9	48.5	33.6	56.5	70.6	<.001‡	49.3	ND
Dysphagia	43.1	53.5	71.5	57.8	74.3	52.8	<.001‡	58.8	ND
Ataxia	19.1	15.7	34.4	9.6	61.7	87.7	<.001‡	36.5	ND

Table 3: (Cont'd): PSROP Patient Characteristics

Characteristics	Site 1 (n = 209)	Site 2 (n=198)	Site 3 (n=186)	Site 4 (n=199)	Site 5 (n=206)	Site 6 (n=163)	Site Variation Significance (P)	Full Sample (n=1161)	National Data*
Acute confusion	10.5	22.7	62.4	9.1	25.7	30.1	<.001‡	26.1	ND
Bowel/bladder incontinence	64.1	77.8	83.9	57.3	73.3	55.8	<.001‡	68.9	ND
Prerehabilitation health care									
Mean no. of days from stroke onset to rehabilitation	15.3	13.0	12.9	21.7	10.0	9.1	<.001†	13.8	ND
Mean acute hospital LOS preceding rehabilitation	10.1	9.0	7.5	8.9	6.8	8.2	.006†	8.6	ND

NOTE. For U.S. patients, n=1161.
Abbreviations: ND, no data; TIA, transient ischemic attack.
*National data from eRehabData.com, unweighted data. See text.
†ANOVA.
‡Chi-square test.
§eRehabData impairment group code reports.

severity of illness, functional status measures), (2) process variables (eg, treatments, interventions), and (3) outcome variables (eg, discharge functional status, discharge severity of illness, discharge destination)

Point-of-care data. An important component of CPI is its attention to the process of care that the patient actually receives; it addresses interventions and patient management strategies. CPI typically relies on information contained in patient medical records, which trained data collectors abstract after patient discharge. The team was confident that many identified acute care hospital and rehabilitation study variables could be obtained from existing documentation at their respective sites. However, they strongly believed that existing patient records did not document adequately specific activities and interventions provided by rehabilitation specialists (eg, physical, occupational, and speech therapists); much patient documentation is oriented to the needs of payment or reimbursement systems. The team agreed that the ability to capture details of what rehabilitation specialists do on a daily basis is essential to opening the black box of rehabilitation care and strongly recommended that we first determine how to get all members of the rehabilitation team to describe accurately what they do. Thus, the concept of point-of-care intervention documentation was incorporated into the study design. This initial taxonomy for stroke rehabilitation is described in detail by DeJong et al.[12]

Intervention taxonomy (documentation) development—the black box. Discipline-specific specialty teams with representation from each participating IRF met via teleconferences from June 2000 through January 2001 to conceptualize and then create discipline-specific intervention documentation forms to record activities and interventions used with stroke rehabilitation patients. This iterative process took approximately 9 months, because specialty teams learned quickly that what is practiced in 1 site is often different from other sites. Clinicians also realized that definitions of common terms differ from site to site and practitioner to practitioner. This is the black box of stroke rehabilitation—What is it that therapists and other stroke care clinicians provide to stroke patients? How are activities or interventions defined and described to others?

The study's physicians, nurses, psychologists, social workers, and physical, occupational, recreational, and speech therapists made a first attempt to identify these differences within their practices by creating an intervention documentation form to include a taxonomy of activities used in each clinical area.[12] This work incorporated practices and definitions in existing frameworks—for example, Occupational Therapy Practice Framework and Guide to Physical Therapist Practice and the level of intervention intensity clinicians thought was needed to capture a complete and accurate picture of the contribution made by that discipline to rehabilitation care (beyond what was already contained in traditional medical record documentation). In addition to developing the content of its documentation form, each rehabilitation discipline decided on the frequency with which its form should be completed. The taxonomy provides a format into which clinicians document actual interventions performed with patients. It does not suggest treatment strategies or changes to routine practice.

Intervention documentation forms were standardized for all sites. Because development efforts included representatives from each participating site, the forms contain interventions that may be specific to 1 or more sites but are not used by all. For example, physical therapists in only 1 facility used constrained induced movement therapy, a different site used pet therapy, and several sites used grocery carts as an assistive device. These "unique" interventions are included on each site's form, even though most places do not use them. Therapists were trained to record only what was done in the actual care process at each site.

What is in the black box of stroke rehabilitation? A partial picture of the black box is presented in appendixes 1 through 3, which contain 3 therapy intervention documentation forms. Therapy-specific interventions are associated with therapy-specific activities, and time spent within each is recorded. The physical therapy (PT) form, for example, contains time spent on specific functional activities (eg, sitting, transfers, gait) and interventions (eg, balance training, cognitive training, strengthening, education) used with each activity. In addition, the PT form captures time spent on formal patient assessment and on home and worksite evaluations. In the case of group therapy, therapists record and include the number of patients, therapists, and assistants involved in the group. Other therapy intervention documentation forms (occupational therapy [OT] and speech language pathology [SLP]) also contained in appendixes 2 and 3 follow a similar format to capture the amount of time spent on specific activities (eg, dressing, transfers, community integration for OT; verbal expression, problem solving, pragmatics for SLP) and specific interventions within each activity (eg, strengthening, balance training for OT; visual cueing, auditory

Table 4: PSROP Process Variables

Variables	Site 1 (n=209)	Site 2 (n=198)	Site 3 (n=186)	Site 4 (n=199)	Site 5 (n=206)	Site 6 (n=163)	Site Variation Significance (P)	Full Sample (n=1161)	National Data*
Mean LOS (d)	21.5	18.2	20.5	16.3	20.2	14.4	<.001†	18.6	17.7
Mean PT (median)									
No. of days	15.7 (15)	12.3 (11)	13.5 (12)	13.7 (14)	14.0 (12)	8.0 (7)	<.001†	13.0 (12)	ND
No. of minutes	910 (865)	775 (653)	903 (675)	816 (810)	709 (586)	670 (580)	<.001†	800 (725)	ND
No. of minutes per day	43.1 (43.5)	40.8 (42.0)	42.3 (40.3)	50.0 (50.8)	35.2 (38.6)	45.9 (52.8)	<.001†	42.8 (43.0)	ND
Mean OT (median)									
No. of days	10.6 (10)	11.4 (10)	13.0 (11)	12.5 (13)	12.9 (10.5)	5.5 (4)	<.001†	11.1 (10)	ND
No. of minutes	655 (575)	764 (638)	913 (715)	803 (745)	677 (615)	446 (360)	<.001†	715 (625)	ND
No. of minutes per day	30.8 (30.6)	40.7 (41.2)	42.8 (43.2)	49.3 (50.4)	33.4 (36.9)	31.2 (32.3)	<.001†	38.1 (39.1)	ND
Mean SLP (median)									
No. of days	8.9 (7)	11.3 (10)	11.9 (10)	8.0 (8)	13.5 (11)	ND	<.001†	10.7 (9)	ND
No. of minutes	425 (355)	625 (500)	749 (560)	360 (315)	735 (613)	ND	<.001†	576 (438)	ND
No. of minutes per day	18.8 (20.0)	32.5 (35.5)	34.6 (35.0)	22.5 (20.8)	36.0 (38.6)	ND	<.001†	28.8 (29.5)	ND
Oxygen use (%)	11.0	0	18.3	3.5	53.4	11.0	<.001‡	16.5	ND
Tube feeding use (%)	13.4	7.1	18.8	7.5	43.7	8.6	<.001‡	16.9	ND
Antidepressant use (%)	32.5	39.9	64.0	43.2	68.5	50.3	<.001‡	49.5	ND
Antipsychotic use (%)	5.7	6.6	4.8	3.0	27.7	6.1	<.001‡	9.2	ND
Opioid pain medication use (%)	8.1	24.8	39.3	16.6	33.5	12.3	<.001‡	22.5	ND
Antiseizure medication use (%)	16.3	14.7	29.0	11.1	21.8	15.3	<.001‡	18.0	ND

NOTE. For U.S. patients, n=1161.
*National data from eRehabData.com, unweighted data. See text.
†ANOVA.
‡Chi-square test.

strategies for SLP). One therapy intervention documentation form was completed for each patient treatment session. Rehabilitation clinicians may provide overlapping services as in the case of physical therapists and occupational therapists who may both, for example, provide balance training. In such instances, therapists from each discipline included discipline-specific applications of the overlapping activities and interventions in their taxonomies. The date and time of therapy was included on each intervention documentation form so that frequency of therapy for specific days of the week could be calculated.

In contrast to the therapy disciplines, other rehabilitation disciplines created intervention documentation forms to meet their needs of capturing information not contained in traditional rehabilitation documentation. The physician form, for example, captured time spent in care management discussions, education of patient/family or medical staff, and supportive activities such as contact with payers and dictation of support letters. The social work form contained information about insurance coordination, crisis intervention, team collaboration, and family communication. Physicians and social workers created multi-day forms of patient interaction, with 1 column completed per day, to capture information not documented in traditional documentation. The nursing intervention documentation form was completed for each nursing shift; it contained only information deemed important to the rehabilitation process but not documented elsewhere (eg, frequency of skin checks, frequency and reinforcement of patient/family teaching). Information from these disciplines is not included in this supplement and will be explored in the future to complete the multidisciplinary picture of stroke rehabilitation care. All intervention documentation forms are available on request.

Intervention documentation training and reliability. During a 3-month pilot test period after development of each form, practicing clinicians who worked on form development used their draft forms during patient treatment sessions and solicited impact assessments from clinician colleagues. Discipline-specific weekly teleconferences provided the forum for clinicians to discuss pilot findings and agree to add, edit, or delete items from the form. Each discipline's form was finalized after this 3-month period (January–March 2001).

IRF clinicians were trained to use intervention documentation forms via discipline-specific train-the-trainer teleconferences attended by a lead clinician in each specialty from each IRF. The project team facilitated this training for each clinical specialty using a training manual that included paper and

electronic copies of the intervention documentation forms, instructions for completing the forms, and definitions for all terms used on the forms. Written case studies were included; 1 case study was used to demonstrate how to complete each form based on a patient scenario. Additional case studies were used to evaluate trainees' understanding of instructions by providing examples of how to use the form for different patient scenarios.

After the telephone training session, each clinical leader conducted on-site training sessions for their coworkers. Teleconferences for each group were held throughout the 2 months following training to provide clinicians the opportunity to discuss implementation issues and ask questions of their peers in other participating institutions.

Each site incorporated auditing of intervention documentation form use into routine site practices. Typically, a second therapist (usually the lead therapist) observed a patient session and completed a separate intervention documentation form based on what was observed. The therapist providing the session completed a form as per protocol and the 2 were compared. The lead therapist reviewed and discussed differences in completion with the practicing therapist.

Intervention documentation form use. Rehabilitation intervention documentation forms were completed for each therapy session and nursing day for each study patient. After patient discharge, completed documentation forms (141,511 forms in all) were transmitted to the project office for optical character recognition interpretation and incorporation into the project database.

Intervention documentation validity. Face validity was built into the therapist intervention documentation forms, because they were developed and used by site therapists as described above. Clinicians came to agree with the content of their respective forms by discussing findings from the pilot test and then agreeing to add, edit, or delete items from the form (content validity).

Predictive validity was assessed as described in other articles[13-16] in this supplement by showing significant effects on outcomes of therapist interventions. For example, the amount of variation explained in discharge FIM score, controlling for patient characteristics (including admission FIM score, severity of illness, demographic factors), was 40% for moderate strokes and 45% for severe strokes. When total time per day spent on PT, OT, and SLP was added, there was no increase in variation explained for discharge FIM, consistent with previous findings by Bode et al.[17] However, when time per day spent in specific PT, OT, and SLP activities was added, the amount of variation explained increased to 52% for moderate strokes and 68% for severe strokes, adding 12% to 23% explanation of variation, respectively, in discharge FIM score.

Postdischarge chart review. Postdischarge chart review was facilitated by the CSI software system that allows for both the input of severity-of-illness data and the creation of auxiliary data modules (ADMs), which are sets of study-specific data elements that are collected in addition to patients' illness severity information. The PSROP clinical team identified and defined all patient, process, and outcome variables to include in the PSROP ADM. Using laptop computers, data collectors at each participating IRF entered chart review data into the CSI software system.

The CSI: disease-specific severity-of-illness data (signs and symptoms). The signature component of the CSI software system is the disease-specific severity system. The CSI is an objective method to define illness severity based on individual signs and symptoms of patients' diseases. Explicit severity criteria were developed by Susan Horn in conjunction with expert clinician panels, originally at the Johns Hopkins Hospital between 1980 and 1992, for each ICD-9-CM diagnosis code or group of similar diagnosis codes. To keep severity criteria up to date with medical practice, the criteria are reviewed and updated via physician panel discussions with each application of the CSI. The CSI defines severity of illness as the physiologic and psychosocial complexity. presented to medical personnel due to the extent and interactions of a patient's disease(s).[8,18-24]

Inputs to the CSI include over 2200 disease-specific and age-specific severity criteria including physical findings, historical factors, physiologic parameters, and laboratory results at specified levels of abnormality found in a resident's chart. Treatments provided do not contribute to severity of illness. For example, intubation is not a severity criterion; severity criteria include patient signs and symptoms that led to a clinical decision to intubate (eg, respiratory acidosis, absent breath sounds, cyanosis).

Disease-specific criteria sets are determined by ICD-9-CM codes assigned routinely by trained facility diagnosis-related group (DRG) coding personnel. CSI data collection is performed via retrospective chart review after patient discharge, and thus, all diagnoses assigned by the facility diagnosis coder appear on a front or summary sheet in each patient's chart. The CSI data collector enters the list of diagnosis codes into the CSI software system, which then displays disease-specific criteria to a trained data collector who abstracts the signs and symptoms that address the criteria from the patient's medical record for specified time periods. It is important to note that the existence of a diagnosis does not indicate the extent of the disease. The CSI substantiates the diagnosis and allows for stratification based on documented patient signs and symptoms.

The stroke criteria set involves the neurologic, musculoskeletal, cardiovascular, and respiratory systems; vital signs; and laboratory values. The presence of a stroke ICD-9 code (eg, 430 [subarachnoid hemorrhage]) prompts for questions from the stroke criteria set, as listed in appendix 4: highest blood pressure, degree of alertness, ataxia, aphasia, dysarthria, dyspnea, perceptual and sensation impairment, dysphagia, hemiplegia, lesion level, time postinjury, acute confusion, and others. Each criterion is followed by response choices for the data collector to select; possible responses are presented in decreasing order of severity. Responses for the stroke dysphagia question, for example, include unable to swallow liquids, unable to swallow solids, other dysphagia, and no dysphagia. The data collector selects the appropriate response based on information found in the patient's chart; data collectors are trained to select the most severe response (by order of presentation). A disease-specific criteria set exists for each group of similar ICD-9-CM codes; the CSI contains over 5500 criteria sets for specific diagnoses in 5 health care settings (acute care, rehabilitation, ambulatory, long-term care, hospice) with details similar to the stroke criteria set in appendix 4.

In the PSROP, each CSI criterion was answered separately for 3 time periods: admission to rehabilitation (first 24h), discharge from rehabilitation (discharge day), and maximum. (Maximum CSI score covers the full rehabilitation stay, including admission and discharge periods.) The maximum score reflects the most abnormal signs and symptoms, regardless of when they occur during the stay.

CSI severity scores reflect the interactions of various health conditions and diseases, as derived from variables in the disease-specific criteria sets. The CSI severity calculation engine assigns a severity weight to each criterion response, which then contributes to a severity rating for each diagnosis for each review period. To compute the overall severity score for a

Table 5: PSROP Outcome Variables

Variables	Site 1 (n=209)	Site 2 (n=198)	Site 3 (n=186)	Site 4 (n=199)	Site 5 (n=206)	Site 6 (n=163)	Site Variation Significance (*P*)	Full Sample (n=1161)	National Data*
Complications									
Any mental disorder diagnosis (%)	61.2	50.0	56.5	58.8	63.6	19.0	<.001†	52.6	ND
Depression diagnosis (%)	10.5	11.6	12.4	4.5	29.1	4.9	<.001†	12.5	ND
Pneumonia diagnosis (%)	5.3	10.6	9.7	4.5	17.0	2.5	<.001†	8.4	ND
DVT diagnosis (%)	4.8	2.0	7.0	4.0	11.7	3.7	.001†	5.6	ND
UTI diagnosis (%)	29.2	28.3	35.5	14.1	50.5	12.3	<.001†	28.9	ND
Electrolyte imbalance diagnosis (%)	6.7	29.3	38.7	5.5	32.5	12.9	<.001†	20.9	ND
Anemia diagnosis (%)	30.1	11.1	8.1	6.5	34.0	1.2	<.001†	15.9	ND
Falls (%)	21.5	12.1	12.9	9.6	9.2	12.9	.002†	13.1	ND
Elevated white blood cell count (>11.0 × 10^9/L) (%)	10.1	8.6	26.9	10.6	27.7	8.6	<.001†	15.5	ND
Severity (CSI) during rehabilitation									
Mean maximum CSI score	31.4	19.0	39.7	20.8	47.5	29.6	<.001‡	31.4	ND
Mean increase in severity (maximum − admission)	11.9	6.2	12.7	5.6	17.5	9.9	<.001†	10.7	ND
Mean discharge CSI score	9.8	1.2	16.8	9.1	16.7	9.6	<.001‡	10.5	ND
Mean gross medical improvement (maximum − discharge CSI score)	21.6	17.8	22.8	11.7	30.7	20.0	<.001‡	20.9	ND
Mean net medical improvement (admission − discharge CSI score)	9.7	11.7	10.1	6.1	13.2	10.1	<.001‡	10.2	ND
FIM score									
Mean discharge total FIM score	86.9	91.7	73.4	95.0	84.7	91.3	<.001‡	87.2	76.2
Mean increase in total FIM (discharge − admission score)	26.8	27.0	25.9	24.0	30.1	23.2	<.001‡	26.2	19.5
Mean discharge motor FIM score	60.0	64.8	52.7	66.9	62.4	64.4	<.001‡	61.9	51.8
Mean increase in motor FIM score (discharge − admission)	22.4	22.6	21.4	20.2	24.6	20.4	.003†	21.9	16.3
Mean discharge cognitive FIM score	27.0	26.9	20.7	28.1	21.9	26.9	<.001‡	25.2	
Mean increase in cognitive FIM score (discharge − admission)	4.4	4.2	4.6	3.8	5.2	2.8	<.001‡	4.2	ND
Discharge destination (%)									
Community vs institution							<.001†		
Community discharge includes home	82.3	84.8	73.1	90.0	72.8	82.8		81.0	70.6
Inpatient institutional discharge	17.7	14.1	26.9	10.1	26.2	16.0		18.5	28.5
Died	0.0	1.0	0.0	0.0	1.0	1.2		0.7	0.3
Home only	81.8	80.8	69.4	81.4	72.3	82.8	.003†	78.0	67.5

NOTE. For U.S. patients, n=1161.
*National data from eRehabData.com, unweighted data. See text.
‡ANOVA.
†Chi-square test.

patient, the severity scores for all diagnoses are combined using disease-specific weighting rules that reflect the interaction of the diagnoses. The overall patient severity level is scored on a continuous scale with nonnegative integer values that are not subject to any preset maximum limit. The more abnormal the signs and symptoms, the higher the score, indicating that that patient is more severely ill. For example, a patient with stroke and congestive heart failure (CHF) probably would have a higher severity score than a patient with stroke alone. The CHF diagnosis does not indicate higher severity, but the signs and symptoms that determine acuteness of the disease contribute to the patient's overall severity of illness. If the CHF is controlled and the patient exhibits no abnormal symptoms of the disease, the diagnosis will not contribute to the overall severity score. If, however, the patient exhibits symptoms of CHF such as shortness of breath, abnormal breath sounds, high pulse, low blood pressure, or respiratory acidosis, these symptoms will contribute to the overall CSI score. Thus, to produce the overall CSI score, CSI logic takes into account the interactions of diseases that are present, their severity levels, and the clinical relations of the diseases.

Often a patient is sickest on admission, and thus the admission and maximum CSI scores will be the same. However, when iatrogenic conditions develop, the maximum CSI score becomes larger (more severe) than the admission score; this is referred to as "increase in severity" in the Results section. Discharge CSI scores typically are the lowest because patients have improved and stabilized throughout the rehabilitation stay. Improvements (decreases) in severity scores were measured in 2 ways: (1) gross medical improvement—a decrease from maximum (full stay) CSI score to discharge CSI score—and (2) net medical improvement—a decrease from admission CSI score to discharge CSI score.

Advantages of this approach to measuring severity of illness include disease specificity, based on a concise, carefully chosen set of relevant physiologic characteristics of the particular

disease rather than based on a standard set of physiologic factors applied to all diseases; comprehensive scope, with over 5500 disease-specific severity criteria sets representing all diseases for which there is an ICD-9-CM code; independence of treatments; and ability to measure severity during specified time windows in the care process. The CSI has been validated extensively in many inpatient, ambulatory, and long-term care settings since 1982.[8,18-24]

Validity of the CSI for stroke rehabilitation patients. CSI criteria for stroke were examined and updated by the project clinical team at the beginning of the project to ensure their face validity for stroke rehabilitation patients. Predictive validity of the CSI and its components for stroke rehabilitation patients are shown elsewhere.[13-16,25-28] Although levels of disability are included in the CSI criteria set for patients with stroke, other components of the CSI remain significant in explaining outcomes after controlling for FIM score and other factors. For example, the amount of variation explained in discharge FIM score by demographic factors alone was 3% for patients with moderate strokes and 4% for patients with severe strokes. When the CSI score and its components were added, the amount of variation explained increased to 15% and 24%, respectively, for patients with moderate and severe strokes.

Patient, process, and outcome data. CPI methodology promotes collection of study-specific patient (in addition to severity-of-illness), process, and outcome data elements, identified and defined by the study team into an instrument referred to as the ADM within the CSI software system. The PSROP ADM contained over 200 variables; most contained date and time fields so that they could be associated with other variables in time sequence, and many have numerous data entries. For example, some data related to vital signs, weight, and pain were collected for each day of the rehabilitation stay, so these single variables have as many entries as the length of stay (LOS). The ADM contained an extensive table of selection choices for each variable; however, data collectors were trained to add to the selection table if a response was not present. For example, the durable medical equipment (DME) selection table contained 173 selection options, but data collectors added another 18 options, including elastic shoelaces and plate guard, during data collection. Appendix 5 presents an outline of the stroke ADM; the outline does not include table selection choices. Rehabilitation activities and interventions contained on each discipline's point-of-care intervention documentation forms (see appendixes 1–3) were classified as process variables also but are not included in the ADM outline version in appendix 5.

Patient variables included age, sex, race, payer source, stroke risk factors, type of stroke (hemorrhagic, ischemic), side of stroke (left, right, bilateral), location of stroke (brainstem/cerebellum, subcortical, brainstem and subcortical, lobar, unknown), admission FIM score (total, motor, cognitive, and all components), case-mix group (CMG), acute care hospital LOS, and date and time of stroke symptom onset (which is subtracted from rehabilitation admission date and time to determine the number of days from stroke onset to rehabilitation admission).

Process variables included rehabilitation LOS, therapy intensity, and specific activities and interventions from point-of-care documentation forms; oxygen use; medications during rehabilitation care; incontinence interventions (eg, indwelling catheters); and nutritional interventions (eg, diet type, tube feeding).

Outcome variables in the ADM included discharge FIM scores, death, discharge destination (home, community, institution), repeat stroke, deep vein thrombosis (DVT), electrolyte imbalance, anemia, urinary tract infection (UTI), pneumonia, falls, mental disorders including depression, and elevated white blood cell count.

The functional performance for each study patient on admission to and discharge from inpatient rehabilitation was obtained via retrospective chart review using the study site's recording of FIM scores. We assumed all clinicians providing FIM data within IRFs as part of standard practice were FIM credentialed; no additional documentation of FIM elements was performed for project purposes. The FIM is a widely used measure of performance across 13 motor areas and 5 cognitive areas and has been found to have "acceptably high" interrater reliability.[29-31] The FIM describes a patient's ability to perform various activities of daily living given various levels of assistance. A patient who is independent in completing a task is rated a 7, one who requires only supervision or contact guard is rated a 5, and one who is dependent is rated a 1 for that specific task. In the context of the PSROP project, admission and discharge FIM scores—total, component (motor, cognitive), and subscores (specific domains, eg, dressing upper and lower body, walking, bowel and bladder incontinence, problem solving)—were collected; however, FIM data were incomplete for 6.5% of the sample. FIM ratings also were used to determine "success" or "failure" in a given activity (ie, increasing the component FIM rating to a predetermined level) and to identify a homogeneous group of study patients for comparison of interventions and outcomes (eg, examining differences in interventions among all patients who were rated a 3 in auditory comprehension on admission).

We assigned each study patient to a CMG following stroke CMG definition rules based on motor FIM score, cognitive FIM score, and patient age (table 2).

Chart review training and reliability. Each IRF medical records abstractor completed a 4-day training session during which efficient and accurate collection of chart review data was explained and practiced. After the training session, each data collector underwent a rigorous manual reliability testing process to ensure complete and accurate data collection that went beyond internal data editing features of the CSI (eg, features that prohibit entry of nonsensible values). Reliability monitoring was conducted at 4 points throughout the PSROP to ensure that data accuracy was maintained. An agreement rate of 95% at the criteria level between each data collector and the project training-team reliability person was required for each reliability test.

Database Management

The comprehensive PSROP database contains all point of care and chart review patient data. Patients and facilities are identified by study identification number only and cannot be identified directly or through linked identifiers. The entire CSI database was exported to SAS statistical software, release 8.2,[a] for analysis.

Data Analyses

For categoric variables, we used contingency tables to examine differences in frequencies and conducted bivariate analyses using chi-square tests to examine differences across sites. For continuous measures we used descriptive statistics, such as average, median, quartiles, and amount of variation (standard deviation [SD], range), and conducted bivariate analyses using ANOVA to test differences across sites and Pearson correlation to test associations of continuous variables. A 2-sided P value less than .05 was considered statistically significant.

RESULTS

The study's database includes 1291 patients from 7 inpatient rehabilitation facilities (1161 U.S. patients, 130 New Zealand patients). Tables 3 through 5 provide data on the key patient, process, and outcome characteristics of the U.S. portion of the PSROP study group and for each site separately.

Patient Characteristics

Table 3 provides a profile of the patient characteristics of the U.S. portion of the PSROP (n=1161) and when available, compares study data to national data available in eRehabData.

Demographic and Health Plan Status

Age and sex. The mean age of the study group was 66.0 years, which is somewhat younger than the mean age in the national eRehabData reference group of 69.7 years. The study group's age did not vary significantly across the 6 sites, but differences were borderline ($P=.059$). The study's sex distribution also did not vary significantly across the sites, but there were proportionately more men in our study group (51.8%) than in the national reference group (46.4%).

Race. The largest difference across the sites was the study group's racial distribution, where 2 sites were predominately white and 2 sites were predominately black. The 2 remaining sites had a more even racial distribution.

Payer. Fifty-six percent of the study group had Medicare as the primary payer, and commercial insurance covered about 30%. A small proportion (2.6%) self paid.

Health and Functional Status

Risk factors. The most frequent stroke risk factors in the study group were diagnoses of hypertension (78.6%) and diabetes (30.8%). A small portion (5.6%) of the sample had an obesity diagnosis; most had never smoked (45.5%) or had quit smoking more than a year before stroke (20%). Most did not have a history of alcohol abuse (12% current or former abuse).

Stroke type and location. Most strokes were ischemic in origin (76.7%) and about evenly divided between right (44.2%) or left side (42.5%) of the brain, which is similar to national data (42.1% and 42.3%, respectively). About 10% of the sample had a bilateral stroke (national data, 3.0%). Most strokes were subcortical or lobar, with a smaller percentage of brainstem and cerebellar infarcts.

FIM scores. Mean admission FIM scores (total, 61.0; motor, 40.1) were slightly higher than in the national reference group (56.7 and 35.5, unweighted, respectively). No national reference group data were available for the FIM admission cognitive component (study data, 21.0). Significant differences existed among sites in mean motor, cognitive, and total admission FIM scores (all $P<.001$).

CMGs. All stroke CMGs are represented in the study group, with the largest number in the more severe CMGs. We combined CMGs into mild (CMGs 101–103), 11.5% of the sample; moderate (CMGs 104–107), 39.6% of the sample; and severe (CMGs 108–114), 42.5% of the sample. The 6.5% of patients who had incomplete FIM data were not classified into CMG groups.

Severity of illness (CSI). Severity-of-illness distributions (higher scores indicate more severe) differed significantly among sites for rehabilitation admission (first 24h), ranging from 12.8 to 30.0 ($P<.001$). The number of diagnosis codes per patient correlated significantly with the patient's admission severity score (Pearson $r=.45$, $P<.001$). Site 5 had the highest severity scores, the most diagnoses, and the second lowest functioning scores. Site 2 had the lowest severity scores; however, it did not have the least number of diagnoses or the highest functioning scores.

Stroke symptoms. As might be expected, hemiplegia was found in the majority of the sample (>86%); bowel and bladder incontinence (as measured by admission FIM bowel and bladder scores of ≤4) was also common. Significant differences were seen among sites; most notably, site 3 had more than twice the number of patients with an aphasia diagnosis than most other sites.

Prerehabilitation Health Care

Time from onset of symptoms to rehabilitation. The study group was admitted to rehabilitation an average ± SD of 13.8±20.8 days (median, 7d; range, 0–319d) after the first onset of symptoms. Interim stays in acute care facilities and skilled nursing facilities are included here. Significant differences were found among sites ranging from 9.1 to 21.7 days ($P<.001$).

Acute care hospital LOS. The average LOS in an acute care hospital before rehabilitation admission was 8.6 days; this differed significantly among sites (site average LOS range, 6.8–10.1; $P=.006$). The mean number of days from symptom onset to acute care hospital admission was 1.4±4.2 days (median, 0d; range, 0–51d).

Process Variables

Process variables are detailed by site and overall in table 4.

Rehabilitation LOS. The mean rehabilitation LOS for our study group was 18.6 days, which is slightly higher than the eRehabData national data (17.7d). Three of our sites had mean LOSs of more than 20 days, and 3 had mean LOSs between 14 and 18 days ($P<.001$).

PT, OT, and SLP. Most PSROP patients received at least 1 session of PT (96.7%) or 1 session of OT (94.9%) during their rehabilitation stay. The vast majority of these (94.6%) had at least 1 session of both PT and OT. Only 2.9% of study patients had neither PT nor OT. One site submitted very few SLP intervention documentation forms; therefore, we excluded that site from SLP analyses. After that exclusion, 93.8% of patients received SLP.

Statistically different numbers of days and numbers of minutes of PT, OT, and SLP are seen among study sites. On average, the 3 therapies averaged about 29 to 43 minutes a day when therapy was provided (PT, 42.8min/d; OT, 38.1min/d; SLP, 28.8min/d).

Treatments. Study sites varied significantly in the use of specific treatments, including use of tube feeding for nutritional support and different types of medications. Forty-nine percent of the sample received an antidepressant medication; 9.2% received an antipsychotic. Almost 23% of study patients received opioid pain medications. Differences in medication use by site[25] and differences in the use of tube feeding to provide nutrition[26] are discussed elsewhere.

Outcome Variables

Outcome variables are detailed by site and overall in table 5.

Comorbidities and complications during rehabilitation. More than half the sample (52.6%) had a documented mental disorder: depression (ICD-9 code 311), 12.5%; organic psychotic condition (ICD-9 code 294), 13.6%; and adjustment reaction (ICD-9 code 309), 8.0%.

The most common medical complications during stroke rehabilitation in our study sample were UTIs (28.9%), anemia (15.9%), and electrolyte imbalances (20.9%); DVTs occurred least frequently (5.6%). We found significant site variation in all measured outcome variables ($P\leq.003$).

Severity of Illness (CSI)

Increase in severity during rehabilitation. Some patients (11%) had an increase in CSI score during the rehabilitation stay, indicating that their illness severity increased during the stay from what it was at admission. The mean increase in severity for the full sample was 10.7 (20.7 on admission, 31.4 at maximum); significant site variation was found ($P<.001$).

Discharge severity and change in severity from admission to discharge. Significant differences were found among sites in gross medical improvement (decrease from maximum [full-stay] CSI score to discharge CSI score) and net medical improvement (decrease from admission CSI score to discharge CSI score; ANOVA, $P<.001$).

FIM Scores

Discharge FIM score and change in FIM scores from admission to discharge. The mean discharge total and motor FIM scores for the study population were higher than for the national sample (total FIM: 87.2 vs 76.2; motor FIM: 61.9 vs 51.8, respectively); larger increases in total and motor FIM scores also were seen in the study sample (total FIM: 26.2 vs 19.5; motor FIM: 21.9 vs 16.3, respectively). Data for cognitive FIM components are not provided in the national data. Study sites differed significantly in mean motor, cognitive, and total discharge FIM scores (all $P<.001$).

Low FIM scores and high severity scores. As seen in table 3, the 2 facilities (sites 3 and 5) that had the lowest functioning patients, as measured by admission FIM scores, also had the highest severity ("sickest") patients, as measured by the highest admission CSI scores.

Rehabilitation Discharge Destination

Most study patients (81%) were discharged from the rehabilitation center to a community setting and the vast majority of these were to the resident or family home (78%). This compares with national statistics of 70.6% and 67.5%, respectively. The study sample had about double the percentage of deaths (0.7%) when compared with the national sample (0.34%).

DISCUSSION

The wide-ranging effects of stroke are a challenge for determining the right match between a stroke survivor's needs and the appropriate rehabilitation services. Failure to find the right fit can result in too little or too much care for a patient's individual needs. We cannot clinically and fiscally allocate appropriate rehabilitation services for every patient with stroke without stronger detailed scientific evidence showing the effectiveness of poststroke rehabilitation interventions. By using the CPI approach, the PSROP assembled a comprehensive database providing the opportunity to examine the complex interplay of patient and process factors and their impact on stroke patient outcomes.

Because of the central role played by the project team in all aspects of CPI, this approach can be characterized as a form of participatory action research—a bottom-up approach that values the participation of those actually engaged in the care-providing process and garners their participation in implementing study findings. CPI encourages new findings, even those that challenge conventional wisdom and long-standing practice.

During this study, there were extraordinary contributions of clinical expertise and time to develop new intervention documentation forms by clinical team members at each IRF. The inclusive nature of the CPI approach retained clinician participation for more than 5 years with no financial rewards. Physicians, therapists, and social workers, among others, realized that better understanding of the details of everyday practice (obtained from data, not expert consensus) and the association of these details with patient outcomes can make great contributions to better outcomes for patients with stroke and better training and practice techniques for clinicians. The level of detail about rehabilitation care that became a part of the supplemental intervention documentation forms had never been documented before and provided tremendous potential to discover treatments that are best for specific patient types.

The CSI enabled us to go beyond controlling only for stroke severity: it allowed us to control for many complex comorbidities common to patients with stroke (particularly those with severe stroke), reflecting more accurately the realities of clinical practice. The strength of the CSI's mechanism for compensating or adjusting for differences among patients allows for a more powerful assessment of the effectiveness of therapeutic interventions. The CSI's use of very specific, disease-oriented questions produced a highly sensitive measure of severity that could not be produced by using diagnosis and/or procedure codes alone or a limited, fixed set of physiologic criteria no matter what the underlying diagnoses may be. Diagnosis codes indicate existence of disease; they do not indicate extent of disease.

Study sites with higher severity-of-illness scores tended to have lower functioning scores (FIM) on admission. The pattern continued at discharge where again, sites with higher discharge severity scores tended to have lower functional scores. Similarly, study sites with lower severity scores tended to have higher-functioning patients (see tables 3, 5). Study sites that had higher severity-of-illness scores also had higher use of more intensive treatments such as oxygen use and nutritional tube feedings (see table 4).

Limitations

CPI methodology relies on the expertise of participating facility clinicians to guide the development of high-level study hypotheses and identify critical data elements to study. As such, these clinicians are aware of study data elements as they provide care and complete point-of-care intervention documentation forms or perform routine documentation practices. This could be construed as introducing treatment bias; however, the number of clinicians who participated in the development of study instruments was a very small subset of all clinicians who cared for over 1200 stroke rehabilitation patients in 7 facilities in 2 countries. Intervention documentation forms and project hypotheses were designed to capture descriptions of actual practice, not to alter practice patterns. In addition, the novelty of attention to specific study questions would wane over the course of an extended patient enrollment period (8mo to 2y, depending on site size and stroke volume).

As much as supplemental point-of-care intervention documentation forms provide an unprecedented level of detail about rehabilitation interventions, they also have intrinsic limitations. Add-on documentation to traditional IRF practices increases the documentation burden of front-line staff and allotted documentation time may not be sufficient to ensure complete documentation of both. Intervention documentation form training was conducted via a train-the-trainer approach using a lead clinician in each rehabilitation discipline in each IRF. Thus, the training of most clinicians depended on the expertise and time availability of the IRF trainers. Monitoring of documentation accuracy became an obligation of each IRF. The project clinical team received reports of IRF auditing processes and findings but did not intervene directly to determine the level of accuracy of

documentation form completion. The project also depended on each IRF to package all intervention documentation forms and send them to the project office for scanning into the project database. Despite these limitations, significant variation in outcomes was found because of differences in time spent per day in various therapy activities.[14-16]

The original intent of the PSROP was to collect data from both the acute care hospital and rehabilitation records to cover the full poststroke course for each patient. However, budgetary and time constraints, as well as lack of convenient access to acute care charts, resulted in complete data from acute care hospital records being collected for only a small portion of the study population. In the end, data collection focused primarily on the rehabilitation stay. This led to lack of ability to control for some patient and process variables that could affect functional outcomes—for example, initial stroke severity (CSI score in acute care), blood pressure, temperature, and glucose levels in the early poststroke period; acute care complications such as seizures; and details of therapies and medications received during acute care hospitalization.

In the initial planning stages, efforts were made to identify and use an objective, validated measure of initial stroke severity (ie, the National Institutes of Health Stroke Scale), but no standard measure was in use across all participating IRFs. Hence, we did not include such a measure. We also did not assess admitting criteria for each IRF, which may have had an effect on types of patients admitted and, thus, types of patients included in the study.

A physiologic severity indexing system, such as the CSI, is limited by data availability. Credentialed DRG coding personnel at each facility assign ICD-9-CM codes as part of standard operating IRF procedures; it is these codes that determine reimbursement. We did not evaluate the credentialing procedures, nor did we audit code assignment. However, the difference in average number of ICD-9-CM codes assigned in facilities (range, 6−15) is curious. A smaller number of ICD-9-CM codes may result in lower severity of illness when using a system that is built on ICD-9-CM coding. Indeed, the facility with the highest average number of ICD-9-CM codes (15.4) did have the highest mean severity-of-illness score (30). However, the facility with the lowest average number of ICD-9-CM codes (6.0) did not have the lowest mean severity scores; there were 2 facilities with lower admission and maximum mean severity scores. If laboratory tests are not ordered, findings are not clearly reported, or complications are not documented, the severity or incidence rate for the related conditions will be lower. The incidence and type of test ordering and availability of information was not uniform across sites and could account for a significant portion of the site variability reported in CSI scores. However, the CSI and/or its components were significant predictors of various outcomes.[13-16,25-28]

Lack of a defined time point for measurement of function after stroke was another limitation of the study. Ideally, the FIM score would be measured at some predetermined endpoint (eg, 90d after stroke onset) for all patients. Use of the discharge FIM scores is less satisfactory, because discharge itself is affected by institutional policies, patient preferences, socioeconomic concerns, insurance coverage, rate of recovery, and other variables.

The rehabilitation setting database created from this project is extremely rich in detail. Of course, this leads to an additional limitation—not all data are reported in this supplement. We plan future publications that capture descriptions and contributions (intervention documentation) of other members of rehabilitation care teams, such as nurses and social workers.

Despite these limitations, having micro-level data provided the ability to focus on the individual patient level to explore reasons for our findings. The PSROP was the first application of CPI methodology to a rehabilitation population and process. As with any new application of a process, a certain amount of trial and error occurred. This knowledge will accrue to subsequent CPI studies for other impairment categories and settings, allowing significant incremental improvements in the efficiency, methodology, and reliability of such studies. The knowledge learned also will facilitate completion of CPI process steps 6 and 7 (validation implementation, protocol incorporation) in future work.

CONCLUSIONS

The PSROP created a comprehensive database to assess the importance of such stroke variables as sex, race, severity of illness, baseline level of functioning, and various therapy interventions on patient-centered outcomes. The PSROP allowed us to describe the duration, intensity, and components of treatment regimens. In addition, the PSROP allowed us to discover treatment practices that are associated with better outcomes for patients with various levels of impairment after stroke. These include findings about medications, PT, OT, SLP, timing of rehabilitation, and nutritional support. Subsequent articles in this supplement describe these findings in detail.[13-16,25-28]

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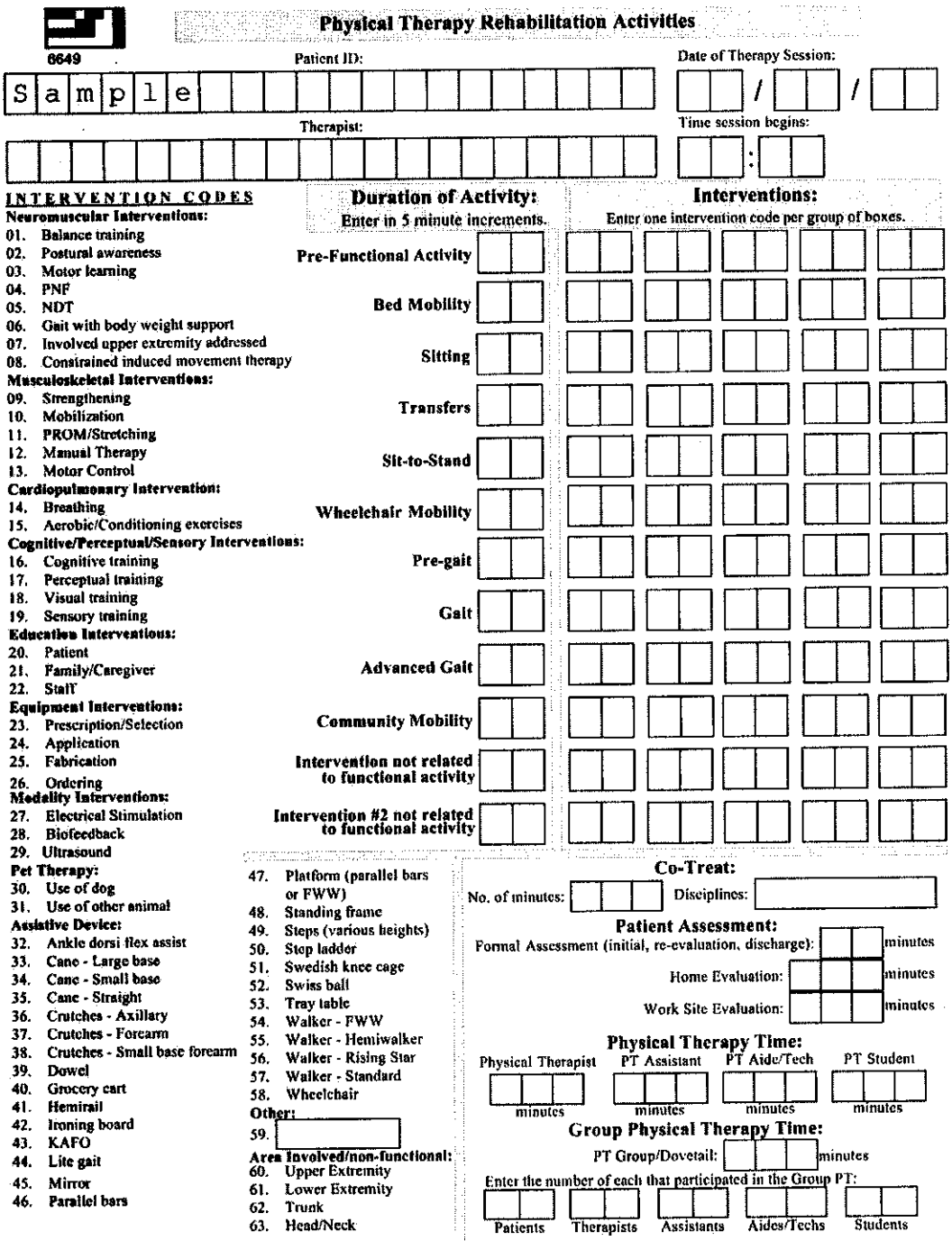
APPENDIX 1: PT INTERVENTION DOCUMENTATION FORM*



Physical Therapy Rehabilitation Activities

8649 Patient ID: Sample

Date of Therapy Session: / /

Therapist:

Time session begins: :

INTERVENTION CODES

Neuromuscular Interventions:
01. Balance training
02. Postural awareness
03. Motor learning
04. PNF
05. NDT
06. Gait with body weight support
07. Involved upper extremity addressed
08. Constrained induced movement therapy

Musculoskeletal Interventions:
09. Strengthening
10. Mobilization
11. PROM/Stretching
12. Manual Therapy
13. Motor Control

Cardiopulmonary Intervention:
14. Breathing
15. Aerobic/Conditioning exercises

Cognitive/Perceptual/Sensory Interventions:
16. Cognitive training
17. Perceptual training
18. Visual training
19. Sensory training

Education Interventions:
20. Patient
21. Family/Caregiver
22. Staff

Equipment Interventions:
23. Prescription/Selection
24. Application
25. Fabrication
26. Ordering

Modality Interventions:
27. Electrical Stimulation
28. Biofeedback
29. Ultrasound

Pet Therapy:
30. Use of dog
31. Use of other animal

Assistive Device:
32. Ankle dorsi flex assist
33. Cane - Large base
34. Cane - Small base
35. Cane - Straight
36. Crutches - Axillary
37. Crutches - Forearm
38. Crutches - Small base forearm
39. Dowel
40. Grocery cart
41. Hemirail
42. Ironing board
43. KAFO
44. Lite gait
45. Mirror
46. Parallel bars
47. Platform (parallel bars or FWW)
48. Standing frame
49. Steps (various heights)
50. Stop ladder
51. Swedish knee cage
52. Swiss ball
53. Tray table
54. Walker - FWW
55. Walker - Hemiwalker
56. Walker - Rising Star
57. Walker - Standard
58. Wheelchair

Other:
59.

Area Involved/non-functional:
60. Upper Extremity
61. Lower Extremity
62. Trunk
63. Head/Neck

Duration of Activity: Enter in 5 minute increments.

Interventions: Enter one intervention code per group of boxes.

- Pre-Functional Activity
- Bed Mobility
- Sitting
- Transfers
- Sit-to-Stand
- Wheelchair Mobility
- Pre-gait
- Gait
- Advanced Gait
- Community Mobility
- Intervention not related to functional activity
- Intervention #2 not related to functional activity

Co-Treat:
No. of minutes: Disciplines:

Patient Assessment:
Formal Assessment (initial, re-evaluation, discharge): minutes
Home Evaluation: minutes
Work Site Evaluation: minutes

Physical Therapy Time:

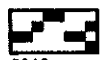
Physical Therapist	PT Assistant	PT Aide/Tech	PT Student
minutes	minutes	minutes	minutes

Group Physical Therapy Time:
PT Group/Dovetail: minutes
Enter the number of each that participated in the Group PT:

Patients	Therapists	Assistants	Aides/Techs	Students

Abbreviations: FWW, front-wheel walker; KAFO, knee-ankle-foot orthosis; NDT, neurodevelopmental treatment; PNF, proprioceptive neuromuscular fasciculation; PROM, passive range of motion.
*Definition of terms available on request.

APPENDIX 2: OT INTERVENTION DOCUMENTATION FORM*



8846

Occupational Therapy Rehabilitation Activities

Patient ID: Sample

Date of Therapy Session: / /

Therapist:

Time session begins: :

INTERVENTION CODES

Neuromuscular Interventions
01. Balance training
02. Postural awareness
03. Motor learning
04. PNF
05. NDT/Bobath
06. Brunstromm
07. Constrained induced movement therapy

Adaptive/Compensatory Interventions:
08. One-handed skills
09. Energy conservation
10. Environmental adaptation
11. Adaptive equipment

Musculoskeletal Interventions:
12. Strengthening
13. Mobilization, manual therapy
14. PROM/stretching
15. Edema control

Cardiopulmonary Interventions:
16. Breathing exercises
17. Aerobic/conditioning exercises

Cognitive/Perceptual/Sensory Interventions:
18. Cognitive training
19. Perceptual training
20. Visual training
21. Sensory training

Equipment Interventions:
22. Prescription/selection
23. Application
24. Fabrication
25. Ordering

Modality Interventions:
26. Electrical stimulation
27. Biofeedback
28. Hot/cold therapy

Education/Training Interventions:
29. Patient
30. Family/Caregiver
31. Staff

Assistive Devices:
32. Cane - Large base
33. Cane - Small base
34. Cane - Straight
35. Crutches - Axillary
36. Crutches - Forearm
37. Crutches - Small base forearm
38. Dowel
39. Grocery cart
40. Hemirail
41. Hi/low table
42. KAFO
43. Parallel bars
44. Platform (parallel bars or FWW)
45. Swiss ball
46. Tray table
47. Walker - FWW
48. Walker - Hemiwalker
49. Walker - Rising star
50. Walker - Standard
51. Wheelchair

Other:
52.

Area Involved:
53. Upper extremity
54. Trunk

	Duration of Activity (Enter in 5 minute increments.)	Interventions (Enter one intervention code per group of boxes.)					
Pre-Functional Activity							
Bathing							
Dressing							
Grooming							
Toileting							
Feeding/eating							
Transfers							
Bed mobility							
Functional mobility							
Home management							
Community integration							
Leisure performance							
Upper extremity control							
Wheelchair management							
Sitting balance/trunk control							
Intervention not related to functional activity							
Intervention #2 not related to functional activity							

Co-Treat:
No. of minutes: Disciplines:

Patient Assessment:
Formal Assessment (initial, re-evaluation, discharge): minutes
Home Evaluation: minutes
Work Site Evaluation: minutes

Occupational Therapy Time:

OT	OT Assistant	OT Aide/Tech	OT Student
minutes	minutes	minutes	minutes

Group Occupational Therapy Time:
OT Group/Dovetail minutes

Enter the number of each that participated in the Group OT:

Patients	Therapists	Assistants	Aides/Techs	Students

*Definition of terms available on request.

APPENDIX 3: SLP INTERVENTION DOCUMENTATION FORM*

Speech & Language Therapy Rehabilitation Activities

16315

Patient ID: Sample

Date of Therapy Session: / /

Therapist:

Time session begins: :

INTERVENTION CODES

Adaptive & Compensatory Strategies:
01. Memory strategies
02. Motor speech strategies
03. Swallowing strategies
04. Diet modification/evaluation
05. Attention/focus strategies
06. Point/gesture strategies
07. Visual strategies/cueing
08. Verbal strategies/cueing
09. Auditory strategies/cueing
10. Tactile strategies/cueing
11. Analysis & summary strategies/cueing

Neuromuscular Interventions:
12. Oral motor treatment/ROM
13. Respiratory treatments
14. Vocal treatments
15. Resonance treatments
16. NDT
17. DPNS
18. Thermal tactile stimulation
19. Postural awareness

Modalities:
20. EMG
21. Biofeedback
22. Electrical stimulation

Devices:
23. Incentive spirometry
24. Memory book/aids
25. Speaking valves
26. Augmentative communication devices
27. Computer
28. Visi pitch
29. Nasal manometer

Perception:
30. Right or left side awareness strategies

Soft Tissue Work:
31. Strengthening
32. Stretching
33. Myofascial release
34. Beckman protocol

Education/ Counseling Interventions:
35. Patient
36. Family/Caregiver
37. Staff

Diagnostic Tests:
38. Video fluoroscopy
39. Fiber optic laryngoscopy
40. Hearing screen
41. Bedside swallowing evaluation
42. Other:

	Duration of Activity (Enter in 5 minute increments.)	Interventions (Enter one intervention code per group of boxes.)
Pre-Functional Activity		
Swallowing		
Face/Neck Mobility		
Speech/Intelligibility		
Voice		
Verbal expression		
Alternative/non-verbal expression		
Written expression		
Auditory comprehension		
Reading comprehension		
Problem solving/reasoning		
Orientation		
Attention		
Memory		
Pragmatics		
Executive functional skills		
Intervention not related to SLP Skills		

Formal Patient Assessment ____ minutes

Supervisory/Team Input ____ minutes

Preparation of Activities ____ minutes

Co-Treat:

Number of minutes: ____ Disciplines

Group Speech & Language Pathology Time:

Enter the number of each that participated in Group Therapy: SLP Group/Dovetail ____ minutes

Patients ____ Therapists ____ Assistants ____ Aides/Techs ____ Students ____

Speech & Language Pathology Time:

SLP	SLP Assistant	SLP Aide/Tech	SLP Student
minutes	minutes	minutes	minutes

Abbreviations: DPNS, direct pharyngeal nerve stimulation; EMG, electromyography; ROM, range of motion.

*Definition of terms available on request.

APPENDIX 4: CSI CRITERIA SET FOR STROKE

Criteria	Selection Choice Options (from highest to lowest severity)
Three-dimensional impairment array	
Degree of impairment	Complete or incomplete high or low quadriplegia, complete or incomplete hemiplegia, upper or lower monoplegia
Ambulatory status	Ambulatory, nonambulatory
Time postinjury	Number of days or number of weeks
Neurologic status	Unresponsive, acute confusion, chronic confusion
Lowest Glasgow Coma Scale score	
Degree of alertness	Coma, stupor, lethargic, drowsy, alert
Seizures	Status epilepticus, grand mal seizure, focal or petit mal seizure focal tremors
Pupil reaction	Bilateral pupil dilation, unilateral pupil dilation
Coordination/balance	Severe ataxia, moderate-mild ataxia, dizziness, vertigo, unsteady on feet, clumsiness, other altered coordination
Sensation alteration	Complete loss of sensation, paresthesia, dysthesia, other sensation alteration
Aphasia	Global aphasia, severe-moderate aphasia, mild aphasia
Dysarthria	No speech, incomprehensible sounds, dysphonia, other dysarthria
Dysphagia	Unable to swallow solids, unable to swallow liquids, other dysphagia
Nausea/vomiting	Persistent vomiting, other vomiting, nausea
Headache	Intense headache, moderate to severe headache, other headache
Dyspnea	Dyspnea at rest, dyspnea on exertion, breathing difficulties
Rales	Rales >50% of lung fields, rales ≤50% of lung fields
Breath sounds	Absent breath sounds in >50 of lung fields, decreased breath sounds in >50% of lung fields, decreased breath sounds in ≤50% of lung fields
Apnea	Apnea, no apnea
Perceptual impairment	Acute decline in perceptual function, chronic perceptual impairment requiring internal or external cues, intermittent perceptual limitations
EKG rhythm	Ventricular tachycardia, >6 PVCs/min, SVT, bigeminy, trigeminy, quadrigeminy, atrial fibrillation, PACs, other ectopics
Highest blood pressure, systolic and diastolic	
Lowest systolic blood pressure	
Highest pulse	
Lowest pulse	

Abbreviations: EKG, electrocardiogram; PAC, premature atrial contraction; PVC, premature ventricular contraction; SVT, supraventricular tachycardia.

APPENDIX 5: PSROP ADM OUTLINE

I. Patient demographics/history
  1. Race, religion
  2. Cardiovascular history
  3. Alcohol, smoking, illicit drug use/history
  4. Before stroke: ambulation capability, ADLs, DME, medication
  5. Education level, career, financial stressors
  6. Acute care LOS

II. Rehabilitation information
  1. Stroke details
    A. Onset of symptoms (date, time)
    B. First medical contact (date, time, location)
    C. Stroke details (side, type/location of stroke, vascular involvement, cerebral edema)
  2. Therapies missed (date, time, reason), oxygen increased requirements during therapy
  3. Mental status assessment
  4. Vitals from nursing progress notes/flow sheets
    A. Daily high temperature, high/low systolic BP, high/low diastolic BP, weight
    B. Suction type/frequency
    C. Lowest oxygen saturation, maximum oxygen requirements
    D. Pain (0–10 scale, location)
    E. Diarrhea/constipation
  5. Bladder and bowel training programs
    A. Indwelling catheter (insertion/removal dates)
    B. Intermittent catheter (insertion/removal dates)
    C. Postvoid residual measurements (each date)
    D. Bladder scan date
    E. Prompted bladder program date
    F. Prompted bowel program date

APPENDIX 5: PSROP ADM OUTLINE (cont'd)

6. Respiratory management
   A. Ventilator start/stop date/time
   B. Tracheostomy start/stop date/time
   C. Sleep apnea
   D. CPAP/BiPAP
7. Nutrition
   A. Dietary consult dates
   B. Type of diet
   C. By mouth nutritional beverage/supplement
   D. Tube feedings
   E. Calorie counts
8. Complications
   A. Pressure ulcer assessment (date, location, stage, width, length, depth, tissue type)
   B. Deep vein thrombosis (date, location)
   C. Fall (date, time, type)
   D. Physical restraints/electronic monitoring (start/stop date/time)
   E. Elevated white blood cell count $>11.0\times10^9$/L (date, value)
9. Medications (varying levels of dosing information based on drug type)
10. Laboratory test results (albumin, pre-albumin, INR, homocysteine, serum drug levels)
11. FIM scores (all FIM data for admission, discharge, and other times of completion)
12. Family/caregiver assessment
   A. Caregivers (who)
   B. Physical support available from caregivers after discharge (some, 24 hours)
   C. Supervision available from caregivers after discharge (some, 24 hours)
13. Discharge
   A. Projected location
   B. Actual location
   C. Reason different
   D. Recommended discharge therapy programs
   E. Support programs
   F. Acute care DRG (if returned to acute care)
   G. Reason for discharge to acute care
   H. Discharge DME

Abbreviations: ADLs, activities of daily living; BiPAP, bilevel positive airway pressure; BP, blood pressure; CPAP, continuous positive airway pressure; INR, international normalized ratio.

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ORIGINAL ARTICLE

Timing of Initiation of Rehabilitation After Stroke

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ABSTRACT. Maulden SA, Gassaway J, Horn SD, Smout RJ, DeJong G. Timing of initiation of rehabilitation after stroke. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S34-40.

Objective: To study associations between days from stroke symptom onset to rehabilitation admission and rehabilitation outcomes, controlling for a variety of confounding variables.

Design: Observational cohort study of 200 consecutive post-stroke rehabilitation patients in each of 6 inpatient rehabilitation facilities.

Setting: Six U.S. inpatient rehabilitation hospitals.

Participants: Patients (N=969) with moderate or severe strokes who had days from stroke symptom onset to rehabilitation admission recorded in their medical records.

Interventions: Not applicable.

Main Outcome Measures: Discharge total FIM, discharge motor FIM, discharge activities of daily living (ADL) FIM, and discharge mobility FIM scores, as well as rehabilitation length of stay (LOS).

Results: Fewer days from stroke symptom onset to rehabilitation admission was associated significantly with better functional outcomes: higher total, motor, mobility, and ADL discharge FIM scores, controlling for confounding variables. For severely impaired patients with stroke in case-mix groups (CMGs) 108–114, the relation was strongest, with F statistics greater than 24.1 for each functional outcome. For patients with moderately severe stroke in CMGs 104–107, fewer days from stroke symptom onset to rehabilitation admission was associated significantly with shorter rehabilitation LOS.

Conclusions: Fewer days from stroke symptom onset to rehabilitation admission is associated with better functional outcomes at discharge and shorter LOS.

Key Words: Cerebrovascular accident; Clinical practice variations; Rehabilitation; Stroke; Treatment outcomes.

STROKE IS COMMON and is a leading cause of disability. Mortality rates from stroke have been declining,[1,2] resulting in more people living with residual disability.[3-5] It is well documented in the literature that rehabilitation plays an important role in functional recovery of stroke survivors, providing quantifiable benefits beyond the natural recovery that occurs without any targeted therapy.[3,6-8]

Unfortunately, existing studies of stroke rehabilitation outcomes are neither clear nor consistent,[3] and debate continues over effectiveness of stroke rehabilitation programs.[9-11] Many rehabilitation providers argue that the acute care hospital payment system encourages acute care providers to discharge patients to rehabilitation before they are medically stable. However, early mobilization and more aggressive rehabilitation are components of stroke unit care thought to contribute to improved outcomes.[12-17]

Optimal timing of rehabilitation after stroke remains controversial. It is an important question to answer because it is modifiable, unlike other predictors of functional recovery after stroke (eg, age, premorbid function). Several studies provide evidence for the benefit of early rehabilitation compared with later intervention in patients with stroke.[3,6,12,18-20] However, interpretation of these studies is limited by heterogeneous definitions, study designs, and methods. For example, early rehabilitation may mean starting rehabilitation anywhere from 3 to 30 days after stroke.[6] Johnston and Keister[21] found that the positive correlation between early rehabilitation and improved functional outcomes disappeared when key patient characteristics, such as functional status on admission, were controlled for. The problem is compounded further by variation in type and severity of strokes, variation in rehabilitation procedures in different settings, and incomplete, vague, or ambiguous documentation of what constitutes each type of therapy.[22,23]

The question of how soon to start rehabilitation after stroke is relevant also in light of recent theories regarding neural responses to injury. Surrounding a cerebral infarct is a zone of cells that potentially are salvageable but are more vulnerable to injury poststroke (the ischemic penumbra). These cells may or may not recover, depending on a number of physiologic factors.[24] Based on animal studies and human imaging studies, there is evidence for neural reorganization thought to be dependent on some form of synaptic plasticity.[24-26] There may be increased potential for cortical plasticity in the 7 to 18 days after injury (animal literature),[27,28] suggesting a critical period to obtain the best recovery after stroke.[24]

On the other hand, rehabilitation in the very early stages after stroke theoretically may harm vulnerable cells via oxidative and/or metabolic stress in concert with reperfusion injury. Many patients show extension of the infarct area by imaging within the first few days after stroke.[29] Even so, increases in infarct volume have not always been shown to correlate predictably with functional outcomes. Two studies in experimentally lesioned animals report a paradoxic exacerbation of brain damage with concomitant enhancement of recovery of function after early rehabilitative interventions.[30,31]

A detailed literature review substantiating the need to examine rehabilitation processes to improve outcomes for specific

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types of patients is presented elsewhere.[32] The purpose of the analyses presented here was to study the associations between days from onset of stroke symptoms to rehabilitation admission and rehabilitation outcomes, controlling for a variety of confounding variables based on data from the Post-Stroke Rehabilitation Outcomes Project (PSROP).

METHODS

The clinical practice improvement (CPI) methodology was used in the PSROP because it captures in-depth, comprehensive information about patient characteristics (including clinical signs and symptoms), rehabilitation processes of care, and rehabilitation outcomes needed to characterize the process of care and ascertain the contribution of individual rehabilitation processes to outcomes.[33] An in-depth description of the study's methods, including issues of validity and reliability, can be found in Gassaway et al[33] in this supplement. In this article, we provide only a summary of the study's extensive methods to help interpret the findings reported here.

PSROP Facilities

Six U.S. inpatient rehabilitation facilities (IRFs) participated in the PSROP and were selected based on geographic location and their willingness to participate; they are not a probability sample of IRFs in the United States. Each site contributed detailed data on about 200 consecutive poststroke patients, for a total of 1161 patients. Patients with stroke from these 6 IRFs constitute a convenience sample.

PSROP Patient Selection Criteria

Each participating IRF obtained institutional review board approval for this observational study and enrolled consecutively admitted patients who met the following inclusion criteria:

(1) Rehabilitation diagnosis of 430 to 438.99, 997.02, or 852 to 853: one of these diagnosis codes was present in the list of *International Classification of Diseases, 9th Revision*,[34] codes in the rehabilitation record.
(2) Age greater than 18 years.
(3) First rehabilitation admission after the current stroke, with the principal reason for admission being stroke. The patient may have had previous strokes and previous rehabilitation admissions for previous stroke(s), but this was the first admission for the current stroke. Current stroke must have occurred within 1 year of this rehabilitation admission.
(4) If a patient was transferred to another setting of care (eg, acute care hospital) and returned to the IRF within 30 days, the patient remained a study patient. If a patient transferred to another setting of care and returned to the IRF after 30 days, participation in the study ended on the day of transfer.

PSROP Study Variables

Three types of study data—(1) patient characteristics (eg, age, sex, race, payer, type of stroke, side of stroke, admission severity of illness, functional status measures), (2) process variables (eg, treatments, interventions), and (3) outcome variables (eg, discharge functional status, discharge severity of illness, discharge destination)—were obtained from multiple sources either at the point of care or from postdischarge chart review in the IRF.

PSROP Data Collection

Point-of-care data. The study's physicians, nurses, psychologists, social workers, and physical, occupational, recreational, and speech language pathology therapists each created a form to include the level of intervention intensity they thought was needed to capture a complete and accurate picture of the contribution made by that discipline to rehabilitation care (beyond what was already contained in traditional medical record documentation). Each rehabilitation discipline developed its own content and decided on the frequency with which its form should be completed. One therapy intervention documentation form was completed for each patient treatment session. Examples of forms used by physical therapists, occupational therapists, and speech-language pathologists are given elsewhere.[33]

Disease-specific severity-of-illness data (signs and symptoms). The Comprehensive Severity Index (CSI) is the study's principal severity adjuster. The CSI is an exhaustive, disease-specific severity system that provides a consistent method of defining severity of illness levels using over 2200 individual patient historical factors, physiologic parameters, laboratory results, and physical findings. In the CSI, severity is defined as the physiologic and psychosocial complexity presented to medical personnel due to the extent and interactions of a patient's disease(s).[33] The CSI was measured separately for admission to rehabilitation (first 24h), discharge from rehabilitation (discharge day), and maximum. (Maximum CSI covers the full rehabilitation stay, including admission and discharge period.) Often a patient is the sickest on admission, and thus the admission and maximum CSI scores will be the same. However, when iatrogenic conditions develop, the maximum CSI score becomes larger (more severe) than the admission score. Discharge CSI scores typically are the lowest, because patients have improved and stabilized throughout the rehabilitation stay.

Additional patient, process, and outcome data. In addition to disease-specific severity-of-illness information, the CSI software system allows for the collection of additional study-specific patient, process, and outcome data elements, identified and defined by the project clinical team into an instrument called the auxiliary data module (ADM). Most variables contain date and time fields so that they can be associated with other variables in time sequence. The PSROP ADM contained over 200 variables, many of which have numerous data entries. For example, some data related to vital signs, weight, and pain, among others, were collected for each day of the rehabilitation stay, so these single variables have as many entries as the length of stay (LOS). Outcome variables in the ADM included discharge FIM instrument scores, LOS, death, and discharge destination. Patient and process variables included living situation, ambulation, activities of daily living (ADLs), and employment before stroke; age; sex; payer source; admission FIM score; case-mix group (CMG) (used for Medicare payment purposes); rehabilitation LOS; and acute admission LOS.[33]

The functional performance for each study patient on admission to and discharge from inpatient rehabilitation was obtained via retrospective chart review using the study site's reporting of FIM scores. We assumed all clinicians providing FIM data within IRFs, as part of standard practice, were FIM credentialed; no additional documentation of FIM elements was performed for project purposes. We assigned each study patient to a CMG following stroke CMG definition rules based on motor FIM score, cognitive FIM score, and patient age.[33,35,36]

Patient sample. From the 1161 PSROP patients, we excluded patients who died and outlier patients admitted to rehabilitation more than 200 days after stroke symptom onset. There were 1031 patients remaining for study from the 6 U.S. rehabilitation sites.

Preliminary analyses showed that admission CMG was a stronger predictor of functional outcome than admission FIM score alone. Therefore, we chose to analyze the 1031 patients within CMG groupings while controlling for admission FIM scores as independent variables in regression analyses. To maintain sample sizes large enough to detect small effect sizes, CMGs were combined into moderate (CMGs 104–107, n=486 patients) and severe (CMGs 108–114, n=483 patients) patient groups. We focused analyses on the 969 patients with moderate and severe stroke, because there were too few patients with mild stroke in CMGs 101 to 103 (n=62).

Processes and Interventions

Timing of rehabilitation after stroke. To determine the relation between days from onset of stroke symptoms to rehabilitation admission and functional outcomes, we defined the following variable: number of days from stroke onset (defined as first symptom onset) to admission to a dedicated rehabilitation unit. Other time intervals were defined as control variables. For example, days from symptom onset to acute care hospital admission was included in the regression models. In some cases, a patient experienced the onset of stroke symptoms during an acute care hospital stay (eg, for a cardiac procedure), yielding a negative number of days from symptom onset to acute care admission. In these cases, we counted the number of days from symptom onset to acute care hospital admission as zero. Similarly, if a patient was receiving therapy in the hospital before onset of stroke symptoms, the number of days between symptom onset and initiation of therapy was counted as zero.

Outcomes

FIM subscores. The FIM provides a useful global measure of functional independence. However, we found that patients with identical FIM scores actually differed markedly in distinct aspects of functioning that are targeted by particular therapies. Therefore, we used FIM subscores indicating impairment in specific domains—such as ADLs, motor function, or mobility—as outcome measures. To obtain the FIM ADL subscore, 6 individual FIM component scores for activities (bathing, eating, grooming, dressing upper body, dressing lower body, toileting) were added. To obtain the FIM mobility subscore, 3 individual FIM component scores for transfers (toilet; bed, chair, and wheelchair; tub and shower transfers) and 2 individual FIM component scores for locomotion (stairs, walk and wheelchair locomotion) were added together. The FIM motor subscore was the sum of the FIM mobility subscore, the FIM ADL subscore, and the FIM component scores for bladder and bowel control.

Statistical Methods

Ordinary least squares regression was used to examine associations between days from symptom onset to rehabilitation admission with each resident functional outcome at discharge, controlling for age, sex, race, ambulation independence before admission, ADL independence before admission, rehabilitation LOS, side of brain affected by stroke, days from symptom onset to acute care admission of 4 or more, acute care LOS of 20 days or more, and admission to IRF after implementation of a new prospective payment system.

All potential predictor variables were checked for multicollinearity; no correlations were greater than .50. Stepwise R^2 selection procedure allowed independent variables to enter and leave each model. The importance of each predictor was determined by its F value. We created the most parsimonious model for each outcome by allowing only significant ($P<.05$) variables to remain in the model. Analyses were performed within subpopulations (CMG groups) of the sample. All analyses were performed with SAS statistical software.[a]

RESULTS

Descriptive Statistics

Characteristics of the 969-patient sample (age, sex, race, payer, stroke characteristics, FIM scores and subscores, severity-of-illness scores, number of days from stroke onset to rehabilitation admission) are shown in table 1. In addition, rehabilitation LOS, discharge destination, and other functional and severity outcome data are presented for the 969-patient sample.

Days From Stroke Symptom Onset to Rehabilitation Admission

We hypothesized that delayed time to rehabilitation admission would be associated with lower functional outcomes, as measured by FIM scores (or subscores) at discharge from rehabilitation. First, we examined the association of days from symptom onset to rehabilitation admission alone as a predictor of discharge outcomes in simple ordinary least squares regression analyses. These findings are presented in table 2. In both groups (CMGs 104–107, 108–114), more days from stroke symptom onset to rehabilitation admission was associated significantly with lower discharge total FIM, discharge motor FIM, discharge mobility FIM, and discharge ADL FIM scores. In moderately impaired patients (CMGs 104–107), days from stroke symptom onset to rehabilitation admission had a P value of .042 or less for all FIM subscores, and in severely impaired patients (CMGs 108–114), days from stroke symptom onset to rehabilitation admission had a P value of .008 or less for all FIM subscores. In the moderately impaired group, more days from stroke onset to rehabilitation admission also was associated significantly with longer rehabilitation LOS ($P<.001$). By comparison, the severely impaired group did not show an association between days from symptom onset to rehabilitation admission with LOS ($P=.39$).

Next we performed multiple regression analyses, allowing many additional patient and treatment characteristics to enter the models for the various discharge outcome variables. The findings are presented in tables 3 and 4. In table 3 we examine patients with moderate stroke in CMGs 104 to 107. When many additional patient (including maximum CSI) and treatment variables were allowed to enter the model, we found that days from stroke onset to rehabilitation admission remained statistically significant and in the same directions as in the single-variable regression analyses. In table 4, we examine patients with severe stroke in CMGs 108 to 114. Again, the findings from table 2 remain when many additional patient (including maximum CSI) and treatment variables were allowed to enter the models. Patient and treatment variables that entered significantly in each of these equations were in the expected directions related to the outcomes.

DISCUSSION

The purpose of the multicenter PSROP was to open the "black box" of rehabilitation and determine, as precisely as possible, how specific elements of the rehabilitation process contribute to clinical outcomes. Timing of initiation of rehabilitation is one of those elements. Consistently, we found that fewer days from onset of stroke symptoms to rehabilitation admission was associated significantly with better functional

Table 1: Study Sample Patient, Process, and Outcome Characteristics

PSROP Variables	N*	Value
Patient Characteristics		
Mean age (y)	969	66.6±14.4
Sex (% male)	969	52.0
Race (%)	969	
White		54.9
Black		25.7
Other, including Hispanic		19.4
Payer (%)	969	
Medicare		58.4
Medicaid		10.6
Commercial		27.7
Self-pay		2.6
Unknown/missing		0.7
Type of stroke (%)	969	
Hemorrhagic		24.5
Ischemic		75.5
Side of stroke (%)	969	
Right		44.3
Left		43.1
Bilateral		9.9
Unknown		2.7
Mean admission total FIM score	969	57.8±18.3
Mean admission motor FIM score	969	37.4±12.3
Mean admission cognitive FIM score	969	20.5±8.3
CMG (%)	969	
Moderate (104–107)		50.2
Severe (108–114)		49.8
Mean rehab admission CSI score	969	21.6±14.0
Mean no. of days from stroke onset to rehab admission	958	13.8±18.7
Process variables		
Mean LOS	969	19.6±10.1
Outcome variables		
Mean maximum CSI score	969	32.3±20.9
Increase in severity (maximum − admission CSI scores)	969	10.7±11.2
Mean discharge CSI score	969	10.5±11.9
Mean gross medical improvement (maximum − discharge CSI scores)	969	21.7±15.0
Mean net medical improvement (admission − discharge CSI scores)	969	11.1±9.9
Mean discharge total FIM score	955	85.2±21.9
Mean increase in total FIM score (discharge − admission)	955	27.3±14.1
Mean discharge motor FIM score	958	60.2±16.8
Mean increase in motor FIM score (discharge − admission)	958	22.8±11.9
Mean discharge cognitive FIM score	964	24.9±7.5
Mean increase in cognitive FIM score (discharge − admission)	964	4.4±4.2
Discharge destination (%)	969	
Community discharge including home		80.1
Home only		76.8
Inpatient institutional discharge		19.9

NOTE. Values are mean ± standard deviation or as otherwise indicated.
Abbreviation: rehab, rehabilitation.
*One site did not use the speech and language pathology intervention documentation forms. Data from the other 5 sites are included here.

outcomes: higher total, motor, mobility, and ADL discharge FIM scores. For severely impaired patients with stroke in CMGs 108 to 114, the relation was strongest, with F statistics greater than 24.1 for each functional outcome.

Also, for patients with moderately severe stroke in CMGs 104 to 107, fewer days from onset of stroke symptoms to rehabilitation admission was associated significantly with a shorter rehabilitation LOS ($P=.038$). The most intuitive reason for this relation is that those patients with less severe strokes and/or medical comorbidities naturally would be able to begin rehabilitation sooner and would also progress faster through rehabilitation, resulting in a shorter LOS. However, this relation was true after controlling for medical comorbidity and complications with the maximum CSI score. Perhaps earlier rehabilitation efforts provide patients with more practice opportunities to maximize functional gains, giving them a head start on entering rehabilitation. Or it could be that the additional stimulation of early rehabilitation enhances blood flow to injured areas and/or the ischemic penumbra, speeding clearance of toxic waste products such as free radicals and enhancing the healing process rather than inhibiting it. The optimal time window for increased synaptic plasticity (as mentioned elsewhere) may also occur early in the poststroke period, allowing for greater gains if rehabilitation is carried out during this critical interval. Additional research in laboratory animals could be done to confirm or refute this hypothesis, but the generalizability of the results in humans would still be uncertain.

Having microlevel data provided the ability to focus on the individual patient level to explore reasons for our findings and whether the findings would disappear when other variables were controlled for. The CSI enabled us to go beyond controlling only for stroke severity: it allowed us to control for many complex comorbidities common to patients with stroke, reflecting more accurately the realities of clinical practice. The maximum CSI score predicted outcomes as expected: a higher

Table 2: Days From Stoke Onset to Rehabilitation Admission: Associations With Discharge FIM Scores and Rehabilitation LOSs*

	Days From Stroke Onset to Rehabilitation Admission as a Single Independent Variable		
Outcome Variable	Coefficient†	*P*	$R^{2‡}$
Moderate Stroke (CMGs 104–107)			
Discharge total FIM score	−.17	<.001	.025
Discharge motor FIM score	−.12	.001	.023
Discharge mobility FIM score	−.07	<.001	.038
Discharge ADL FIM score	−.04	.042	.009
Rehab LOS	.09	<.001	.024
Severe Stroke (CMGs 108–114)			
Discharge total FIM score	−.11	.008	.015
Discharge motor FIM score	−.10	.003	.019
Discharge mobility FIM score	−.04	<.001	.024
Discharge ADL FIM score	−.05	.001	.022
Rehab LOS	.02	.394	.002

*For CMGs 104–107, n=475; for CMGs 108–114, n=469.
†For simple ordinary least squares regression, "+" represents more days from onset to rehabilitation associated with longer rehabilitation LOS and "−" represents more days from onset to rehabilitation associated with lower discharge FIM subscores.
‡The proportion of variation in a specified outcome explained by predictor variables.

Table 3: Regression Results for Outcomes of Discharge FIM Scores and Rehabilitation LOS for Patients With Moderate Stroke in CMGs 104 to 107 (n=475)

	Dependent Variables											
	Discharge Total FIM Score			Discharge Motor FIM Score			Discharge Mobility FIM Score			Rehabilitation LOS (n=480)		
Independent Variables	Coeff	F	*P*	Coeff	F	*P*	Coeff	F	*P*	Coeff	F	*P*
Days from stroke onset to rehab admission	−0.11	8.2	.004	−0.12	11.7	<.001	−0.08	24.8	<0.001	0.05	4.3	.038
Partial R^2		.010			.013			.030			.01	
Age	−0.13	14.4	<.001	−0.12	16.4	<.001	−0.05	15.1	<.001			
Female							−0.69	3.9	.050			
Admission motor FIM score	0.56	44.7	<.001	0.55	55.8	<.001	0.23	44.7	<.001	−0.33	36.6	<.001
Admission cognitive FIM score	0.70	105.4	<.001				−0.07	6.5	.011	−0.09	4.2	.042
Maximum CSI score	−0.12	11.7	<.001	−0.07	5.2	.023				0.09	16.8	<.001
Employed PTA	3.91	12.2	<.001	2.57	7.1	.008	1.10	5.7	.017	1.66	5.9	.015
Ambulate Independently PTA				2.25	4.3	.039	1.02	3.9	.049	1.67	3.8	.050
R^2		.413			.279			.275			.191	

NOTE. Variables allowed in regressions; age, female, admission motor FIM score, admission cognitive FIM score, ambulation independent before admission, ADLs independent before admission, employed before admission, maximum severity score (CSI), rehab LOS, stroke on right side of brain, stroke on left side of brain, bilateral stroke, stroke on unknown side of brain, race, days from symptom onset to acute admission ≥4, acute admission LOS ≥20 days, post PPS.
Abbreviations: Coeff, coefficient; PPS, prospective payment system; PTA, prior to admission.

score (sicker patient) was associated with a lower discharge FIM score and its component scores and also with a longer rehabilitation LOS. These data support the hypothesis that early inpatient rehabilitation for patients with moderate and severe stroke and more days of acute inpatient rehabilitation for patients with severely impaired stroke are associated with better functional outcomes, after controlling for severity of illness. The findings also are consistent with prior literature regarding the importance of such variables as age, sex, race, severity of illness, baseline level of function, and employment before stroke.

It should be noted that the standard deviation of the time interval from stroke onset to initiation of rehabilitation was quite large (see table 1). This variability is at least in part due

Table 4: Regression Results for Outcomes of Discharge FIM Scores and Rehabilitation LOS for Patients With Severe Stroke in CMGs 108 to 114 (n=469)

	Dependent Variables Score														
	Discharge Total FIM Score			Discharge Motor FIM Score			Discharge Mobility FIM Score			Discharge ADL FIM Score			Rehab LOS (n=478)		
Independent Variables	Coeff	F	*P*	Coeff	F	*P*	Coeff	F	*P*	Coeff	F	*P*	Coeff	F	*P*
Days stroke onset to rehab adm	−0.15	26.7	<.001	−0.14	28.2	<.001	−0.05	24.1	<.001	−0.06	24.5	<.001			
Partial R^2		.022			.027			.032			.024				
Age	−0.22	15.3	<.001	−0.20	16.5	<.001	−0.08	14.1	<.001	−0.07	9.5	.002	−0.13	14.0	<.001
Black	−3.75	5.1	.024	−2.85	4.2	.041									
Stroke on right side of brain				−2.36	4.0	.046	−1.22	5.6	.018						
Stroke on left side of brain										1.47	6.8	.009			
Admission motor FIM score	1.22	104.0	<.001	1.18	157.0	<.001	0.44	143.8	<.001	0.47	101.4	<.001	−0.32	18.0	<.001
Admission cognitive FIM score	0.86	63.9	<.001							0.10	5.8	.017	0.14	4.0	.046
Maximum CSI score	−0.16	18.0	<.001	−0.12	17.6	<.001				−0.06	18.7	<.001	0.11	21.9	<.001
Employed PTA	4.87	7.0	.008	4.33	7.8	.006	1.41	4.3	.039	1.79	6.2	.013	2.40	4.2	.042
ADLs independent PTA				3.77	4.5	.034	1.69	4.8	.029				4.91	14.0	<.001
Rehab LOS	0.45	39.6	<.001	0.30	23.9	<.001	0.08	9.1	.003	0.16	32.3	<.001			
Post PPS													−1.91	4.1	.043
R^2		.540			.443			.322			.428			.197	

NOTE. Variables allowed in regressions: age, female, admission motor FIM, admission cognitive FIM, ambulation independent prior to admission, ADLs independent prior to admission, employed prior to admission, maximum severity score (CSI), rehab LOS, stroke on right side of brain, stroke on left side of brain, bilateral stroke, stroke on unknown side of brain, race, days from symptom onset to acute admission ≥4, acute admission LOS ≥20 days, post PPS.
Abbreviation: adm, admission.

to the wide range of practices in delivery of poststroke rehabilitation care that exist between different regions of the country, hospital systems, and provider groups. In some areas, patients sometimes were discharged to skilled nursing facilities before entering inpatient rehabilitation. Hospital bed availability, staffing shortages, insurance coverage, and socioeconomic status of patients all potentially contribute to the variation in the time interval between stroke onset and rehabilitation. Efforts to reduce this variability by prioritizing timely rehabilitation of patients with stroke could result in substantial improvements in patient functional status, reduced LOS, and decreased health care costs.

As mentioned earlier, some have theorized that early aggressive rehabilitation potentially might be harmful to patients with stroke because of increased oxidative and/or metabolic stress on vulnerable cells. It is of interest, therefore, that the most severely impaired group had the strongest association between earlier rehabilitation and better functional outcomes. Presumably, if this theory were true, these severely affected patients would be most vulnerable to any harmful effects of early rehabilitation. In fact, it is this group that apparently gains the most functional benefits from early rehabilitation. These results concur with our findings in subgroup analyses of physical therapy, occupational therapy, and speech-language pathology therapy.[37-39]

This is encouraging news. Although the evidence is not conclusive, the findings from this multicenter study regarding timing of initiation of rehabilitation after stroke suggest that we need not fear implementing early, aggressive interventions for severely affected patients with stroke; on the contrary, it appears to be the best thing we can do to maximize return of function. In addition, moderately affected patients with stroke apparently benefit from early rehabilitation, both in terms of functional outcomes and shorter LOS. Hence, greater efforts to initiate rehabilitation as soon as feasible and to transfer patients to dedicated rehabilitation facilities in a timely manner should result in greater rehabilitation efficiency and improved functional outcomes in most patients with stroke. Lack of a defined time point for measurement of functioning after stroke was a limitation of the study. Ideally, the FIM score would be measured at some predetermined endpoint (eg, 30d after stroke onset) for all patients. Use of rehabilitation discharge FIM scores is less satisfactory, because discharge itself is affected by institutional policies, patient preferences, socioeconomic concerns, insurance coverage, rate of recovery, and other variables. Despite these limitations, these analyses offer opportunities to uncover new insights and to confirm or reject original hypotheses. The significance of the time period between stroke onset and rehabilitation admission provides opportunities to alter care processes to achieve best possible outcomes.

As the population ages and the health care system faces challenges of providing high quality care with limited resources, it is increasingly important to identify the most effective and efficient means of delivering rehabilitation services to patients with stroke. There are enormous challenges inherent in studying a topic as complex as stroke rehabilitation. Strokes and patients with stroke are heterogeneous. Rehabilitation interventions vary in content, process, duration, intensity, and purpose. Functional outcome measures are difficult to define and interpret. The CPI methodology applied in this project enabled a comprehensive and detailed approach to this topic. The findings provide evidence for the importance of early rehabilitation in patients with stroke routinely encountered in clinical practice, and they could help lay the groundwork for future research and possibly randomized controlled trials.

CONCLUSIONS

For moderately and severely impaired patients with stroke, fewer days between onset of stroke symptoms and admission to inpatient rehabilitation is associated with better functional outcomes at discharge. For moderately impaired patients with stroke, fewer days between onset of stroke symptoms and admission to acute inpatient rehabilitation also is associated with shorter rehabilitation LOS. Providers should strive to transfer patients with stroke as soon as possible from an acute care hospital into acute rehabilitation to improve functional outcomes.

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ORIGINAL ARTICLE

Physical Therapy During Stroke Rehabilitation for People With Different Walking Abilities

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ABSTRACT. Latham NK, Jette DU, Slavin M, Richards LG, Procino A, Smout RJ, Horn SD. Physical therapy during stroke rehabilitation for people with different walking abilities. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S41-50.

Objective: To describe how physical therapy (PT) activities during poststroke inpatient rehabilitation vary by admission walking ability and over time.

Design: Observational cohort study.

Setting: Six inpatient rehabilitation hospitals in the United States.

Participants: People receiving poststroke PT (N=715) who were classified as walking at admission.

Interventions: Not applicable.

Main Outcome Measures: Percentage of time spent in 11 activities, percentage of patients who participated in each activity, and the FIM instrument scores.

Results: The majority of PT time was spent in gait activities. Even people with the most limited mobility spent 25% to 38% of PT time in gait activities during the first 6-hour treatment block. Treatment progression was evident, and a shift to more advanced activities occurred over time (eg, less bed mobility and more advanced gait). However, even in the final 6-hour block, a small proportion of time was spent on community mobility activities (1.2%–5.2%), and most people received no community mobility training.

Conclusions: PT activities focused on specific functional tasks at the ability level of each individual patient and provided higher-level activities as patients improved their function. However, although there is increasing recognition that the environment influences task performance, little time was spent in community mobility activities before discharge.

Key Words: Clinical practice patterns; Physical therapy; Rehabilitation; Stroke; Walking.

PHYSICAL THERAPY (PT) is a standard part of rehabilitation after a stroke in most countries, with numerous guidelines recommending that all stroke patients receive PT.[1,2] However, the literature contains few studies that describe precise activities that physical therapists provide to people after a stroke. Recent systematic reviews have provided comparisons of different PT approaches to stroke rehabilitation, but the trials included in the reviews rarely provide specific details about all PT activities used throughout the course of rehabilitation.[3,4]

Some observational studies have explored PT treatment poststroke. A few studies have described how patients spend their time during inpatient stroke rehabilitation, but they have focused more broadly on whether patients were alone or active[5] or have described PT treatment only in terms of duration or frequency of therapy.[6,7] Most studies have involved a limited number of patients[7-9] or have asked therapists about treatment choices for hypothetical patients.[10] A recent study by Bode et al[11] provides among the most comprehensive assessments to date of the pattern of rehabilitation activities during inpatient stroke rehabilitation. However, this study only reported activities that were classified into 2 general categories: function or impairment activities.[11] None of the studies identified examined how specific PT treatments change over time during the course of stroke rehabilitation or by patients' functional statuses.

Without data to describe reliably poststroke PT activities, it is not known whether current practice follows treatment approaches described in the stroke rehabilitation literature. Many recent review articles, textbooks, and stroke guidelines have emphasized a task-oriented approach to therapy.[2,4,12-16] This approach emphasizes practice of identifiable functional tasks, rather than movement patterns for movement's sake alone.[16] This approach to training has several key features. Although there is still a need to address the underlying impairments, the main focus of this training is on specific tasks.[15,16] When task-specific training is occurring, there should be individualization of the training goals (ie, tasks must be at the appropriate level for a patient's ability) and progression of the training goals over time (ie, as the patient improves, tasks should become progressively more challenging).[15] Finally, it is well established that the environmental context of the training influences performance of the task. Therefore, to retrain functional adaptation, it is important that activities are carried out in different settings, including in settings that provide environmental challenges that are similar to those that a patient will experience on return to his/her community.[16] By examining PT activities over the duration of rehabilitation and among patients with different abilities to walk, the incorporation of these principles into current practice can be explored.

This work is part of the Post-Stroke Rehabilitation Outcomes Project (PSROP). A detailed literature review substantiating the need to examine rehabilitation processes to improve outcomes for specific types of patients is presented elsewhere.[17] Also described elsewhere is an introduction on where clinical practice improvement methods fit into the pantheon of biomedical and clinical research methodology.[18] This study builds on

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Table 1: Patient Characteristics, Processes, and Outcome Variables by Amount of PT Received

PSROP Variable	No. of 6-Hour Blocks of PT			
	1 (n=277)	2 (n=233)	3 (n=135)	4 (n=70)
Patient Characteristics				
Mean age (y)	67.1	67.7	66.2	61.1
Race (%)				
White	57.0	56.2	57.8	58.6
Black	23.8	27.5	30.4	30.0
Other, including Hispanic	19.1	16.3	11.9	11.4
Sex (% men)	48.4	49.4	58.5	51.4
Type of stroke (%)				
Hemorrhagic	26.0	20.6	20.0	20.0
Ischemic	74.0	79.4	80.0	80.0
Side of stroke (%)				
Left	42.2	41.6	43.0	41.4
Right	43.7	45.5	44.4	47.1
Bilateral	10.8	10.3	9.6	8.6
Unknown	3.2	2.6	3.0	2.9
Mean admission motor FIM score	46.8	39.5	35.7	31.5
Mean admission cognitive FIM score	22.6	21.3	20.5	19.3
Mean days from onset to rehab admission	10.3	14.0	17.6	16.7
Process variables				
Mean length of stay	12.2	18.3	24.0	31.4
Mean total minutes of PT	471.0	818.6	1157.0	1518.0
Mean total no. of PT sessions	12.1	22.7	30.5	35.6
Outcome variables				
Discharge destination (%)				
Home	83.4	80.7	78.5	85.7
Board and care (assisted living)	1.1	4.7	4.4	2.9
Skilled nursing facility	11.2	11.6	14.1	8.6
Acute hospital (own or other facility)	2.9	1.3	2.2	2.9
Other rehabilitation facility	1.4	1.7	0.7	0.0
Mean discharge motor FIM score (95% CI)	68.2 (66.5–70.0)	64.2 (62.2–66.2)	59.5 (57.0–62.0)	58.5 (55.4–61.6)
Mean discharge cognitive FIM score (95% CI)	26.1 (25.3–27.0)	25.9 (25.0–26.8)	25.4 (24.2–26.7)	25.4 (23.8–27.0)

Abbreviations: CI, confidence interval; rehab, rehabilitation.

earlier work that described the overall treatment activities provided by physical therapists for PSROP patients[19] by exploring how these treatments vary over the duration of inpatient rehabilitation and according to the patients' mobility limitations. We also explored in one example how these data could be used to describe activities associated with mobility outcomes in a very specific and homogeneous group of patients.

METHODS

The methodology governing the full PSROP, provided in this supplement by Gassaway et al,[20] provides a detailed description of the larger study's participating facilities, patient selection criteria, data collection instruments including their validity and reliability, and a detailed description of the project's final study group. The methodology is summarized in Maulden et al.[21] The institutional review boards at Boston University and at each participating inpatient rehabilitation facility (IRF) approved the study.

Patients in PT Subset

For analyses reported in this article, patients who had fewer than 5 hours of PT during their rehabilitation (n=119) and those who had had more than 30 hours of therapy (n=49) were excluded. These exclusions were made based on our data showing that patients in these groups may have had important differences in illness severity and function from the group receiving 5 to 30 hours of therapy. Additionally, patients were excluded if they were classified as using a wheelchair for locomotion on admission. Data analyses in this article are, therefore, based on 715 patients who received between 5 and 30 hours of PT during their rehabilitation stay and were classified as walking at admission, regardless of the level of independence in walking. Demographic data describing the patients are included in table 1.

Instrumentation

The PT intervention documentation form (appendix 1) developed for the PSROP included a taxonomy of information such as targeted activity area, interventions used by the clinician within each activity, and duration of each activity measured in 5-minute increments.[22] Definitions for the activities and interventions contained on the PT intervention documentation form were provided to practicing clinicians and are available on request. One PT intervention documentation form was completed for each PT session a patient received during his/her inpatient rehabilitation stay.

A lead physical therapist from each IRF participated in a train-the-trainer teleconference to learn how to use and teach others to use the PT intervention documentation form. After the teleconference, the lead physical therapists trained colleagues in their respective IRFs.

Each site incorporated auditing of intervention documentation form use into routine site practices. Typically, the lead physical therapist observed a patient session and completed a separate intervention documentation form based on what was observed. The therapist providing the session completed a form as per protocol. The lead therapist reviewed and discussed differences in completion with the practicing therapist.

Face validity was built into the intervention documentation forms because they were developed and used by IRF therapists as described above. Predictive validity was assessed by showing significant effects of PT interventions (and other therapy interventions) on outcomes.[23-25] For example, the amount of variation explained in discharge FIM score, controlling for patient characteristics (including admission FIM score, severity of illness, demographic factors), was 40% for moderate strokes and 45% for severe strokes. When total time per day spent on PT, occupational therapy (OT), and speech-language pathology (SLP) was added, there was no increase in variation explained for discharge FIM, consistent with previous findings by Bode et al.[11] However, when time per day spent in specific PT, OT, and SLP activities was added, the amount of variation explained increased to 52% for moderate strokes and 68% for severe strokes, adding 12% to 23% explanation of variation, respectively, in discharge FIM score.

Functional performance for each study patient at admission to and discharge from inpatient rehabilitation was obtained via retrospective chart review using each study site's reporting of the FIM scores.[1,26] We assumed all clinicians providing FIM data within IRFs as part of standard practice were FIM credentialed; no additional documentation of FIM elements was performed for project purposes.

Data Analysis

Patients were categorized by 2 factors, their functional ability at admission to rehabilitation and the duration of their PT treatment. Patients were first classified according to their functional ability based on their admission score on the FIM locomotion item (description in appendix 2). We created 2 functional groups: (1) score of 1 or 2 on the locomotion FIM item (severe limitation in locomotion) and (2) score of 3 or better on the locomotion FIM item (moderate or less limitation in mobility).

Patients were then categorized based on the duration of PT services. Four categories of patients were created: those who received 1, 2, 3, and 4 six-hour blocks of PT across their episode of care. Because data concerning activities were collected across an entire session and because PT sessions differed in length, each 6-hour block of therapy for patients could contain a variable number of sessions. We, therefore, classified patients using the number of full sessions that would bring the therapy hours the closest to 6, 12, 18, or 24 without including the next time block. For example, patients classified as having 1 six-hour block of therapy received between 5 and 11 hours of PT during their rehabilitation stay with an average total time of 471.0 minutes (95% confidence interval, 458.0–483.9). We examined the content of PT sessions, however, for only the first 6 hours.

Descriptive statistics were derived to examine characteristics of patients within each category, as well as characteristics of their episodes of care. The content of treatment sessions was described first by determining the percentage of all PT time within each 6-hour block spent on examination and evaluation. Examination and evaluation time then was subtracted from total therapy time, and percentage of the remaining time spent in each activity was determined.

Finally, we selected a specific subset of patients to explore a method to refine the description of PT sessions and to describe the association between activities and outcome based on the FIM locomotion item. Based on our earlier descriptive data, we selected patients who received 3 six-hour blocks of PT and who had an admission FIM locomotion score of 1 (totally dependent) to create a somewhat homogeneous group of patients. This group of patients was then further stratified according to their discharge scores on the FIM locomotion item: less than 4 or greater than or equal to 4. The PT sessions for these groups of patients were described in terms of the percentage of time spent in each activity during the first 3 hours of therapy. Three hours was chosen for this analysis because we expected only minimal to moderate effects of natural recovery during that time period, and we wished to minimize the effect of improvements in patients' physical functioning on selection of activities.

RESULTS

The average percentage of time spent in each activity for patients receiving 1, 2, 3, and 4 six-hour blocks of therapy can be found in tables 2 through 5.

Table 2: Characteristics of PT Sessions for Patients With 1 Six-Hour Block of PT

Activity*	% Patients†	Mean % Time‡ (95% CI)
Admission locomotion 1 or 2 (n=174)		
Prefunctional	87.9	19.2 (17.2–21.2)
Bed mobility	58.0	4.3 (3.4–5.2)
Sitting	40.2	3.3 (2.4–4.2)
Transfers	86.2	10.5 (9.3–11.7)
Sit to stand	75.3	6.8 (5.8–7.8)
Wheelchair	40.8	2.1 (1.6–2.6)
Pregait	68.4	7.4 (6.2–8.6)
Gait	97.7	37.9 (35.5–40.3)
Advanced gait	59.2	6.4 (5.2–7.7)
Community mobility	17.8	1.9 (0.9–2.8)
Using cane	41.4	NA
Using ankle-foot orthosis	14.4	NA
Admission locomotion ≥3 (n=103)		
Prefunctional	91.3	21.2 (18.4–23.9)
Bed mobility	25.2	1.0 (0.6–1.5)
Sitting	22.3	1.3 (0.7–1.8)
Transfers	64.1	5.4 (4.0–6.8)
Sit to stand	53.4	3.7 (2.8–4.7)
Wheelchair	13.6	0.6 (0.3–1.0)
Pregait	68.0	8.1 (6.2–10.0)
Gait	100.0	42.6 (39.6–45.6)
Advanced gait	75.7	11.5 (9.2–13.9)
Community mobility	28.2	4.0 (2.3–5.6)
Using cane	58.3	NA
Using ankle-foot orthosis	9.7	NA

Abbreviation: NA, not applicable.
*Activities reported as percentage of time spent outside of examination and evaluation during the block.
†Percentage of patients receiving this activity during the 6-hour block.
‡Mean percentage of total time across patients spent in the activity during the 6-hour block.

Table 3: Characteristics of PT Sessions for Patients With 2 Six-Hour Blocks of PT

Activity*	1 Block		2 Blocks	
	% Patients†	Mean % Time‡ (95% CI)	% Patients†	Mean % Time‡ (95% CI)
Admission locomotion 1 or 2 (n=202)				
Prefunctional	91.1	20.8 (18.8–22.8)	93.1	23.4 (21.3–25.5)
Bed mobility	58.9	4.2 (3.4–4.9)	42.1	2.8 (2.1–3.4)
Sitting	42.6	4.2 (3.1–5.2)	32.7	3.1 (2.1–4.0)
Transfers	86.1	11.8 (10.5–13.1)	80.7	8.5 (7.3–9.8)
Sit to stand	76.7	7.6 (6.6–8.6)	61.4	5.1 (4.3–6.0)
Wheelchair	44.6	2.2 (1.7–2.7)	32.2	1.5 (1.1–2.0)
Pregait	79.7	9.9 (8.6–11.2)	72.3	7.0 (5.9–8.1)
Gait	95.0	35.9 (33.5–38.3)	96.0	38.1 (35.6–40.6)
Advanced gait	39.1	2.8 (2.1–3.5)	57.9	7.2 (6.0–8.4)
Community mobility	6.9	0.5 (0.2–0.7)	23.8	2.9 (1.8–4.1)
Using cane	56.9	NA	61.4	NA
Using ankle-foot orthosis	29.7	NA	100.0	NA
Admission locomotion ≥3 (n=31)				
Prefunctional	90.3	23.0 (17.5–28.6)	93.5	27.0 (20.4–33.7)
Bed mobility	45.2	3.0 (0.8–5.2)	25.8	1.2 (0.2–2.2)
Sitting	32.3	1.6 (0.4–2.9)	19.4	1.7 (−0.1 to 3.5)
Transfers	77.4	7.0 (4.4–9.6)	58.1	4.2 (2.4–6.0)
Sit to stand	61.3	4.4 (1.9–7.0)	41.9	3.3 (1.4–5.2)
Wheelchair	22.6	1.1 (0.3–2.0)	12.9	0.9 (−0.4 to 2.1)
Pregait	64.5	7.3 (4.2–10.5)	61.3	4.9 (2.9–7.0)
Gait	100.0	45.0 (38.3–51.7)	100.0	40.8 (34.7–46.9)
Advanced gait	67.7	5.9 (3.5–8.2)	71.0	10.7 (6.8–14.6)
Community mobility	12.9	1.2 (−0.2 to 2.6)	51.6	5.2 (2.5–7.9)
Using cane	58.1	NA	48.4	NA
Using ankle-foot orthosis	12.9	NA	100.0	NA

*Activities reported as percentage of time spent outside of examination and evaluation during the block.
†Percentage of patients receiving this activity during the 6-hour block.
‡Mean percentage of total time across patients spent in the activity during the 6-hour block.

Frequency of Gait Activity

Regardless of the amount of time spent in the rehabilitation setting and the initial level of locomotor function, patients spent most of their time in PT practicing gait. Even during the first 6 hours of PT sessions, patients spent a higher percentage of time in gait than any other activity. That is, approximately 25% to 45% of time was spent in gait activity across groups of patients versus 18% to 20% of time in prefunctional activity (preparation activity related to an upcoming PT activity), the next highest amount of time. During the last 6-hour block of therapy, 96% of patients who began with a FIM locomotion score of 1 or 2 and 100% of patients who began with a FIM locomotion score of 3 or better engaged in gait activity.

PT Activities and Patient Functional Ability

Physical therapists design plans of care for their patients that are aimed at each patient's ability level to perform physical activities. Patients whose admission locomotion FIM scores were 1 or 2 spent as much as 5.6% of their session time in bed mobility, 6.2% of time in sitting activities, and 15.2% of time in transfers during the initial 6-hour block, whereas patients with an admission FIM locomotion score of 3 or better spent 3.0% of their time in bed mobility, 2.9% of time in sitting activity, and 7.0% of time in transfer activities. This pattern was seen in higher-level activities as well. Patients with an initial FIM locomotion score of 1 or 2 spent up to 37.9% of session time in gait activities and 6.4% of session time in advanced gait activities during the initial 6-hour block of therapy, whereas patients with an initial FIM locomotion score of 3 or better spent up to 45% of session time in gait activities and 11.5% of session time in advanced gait activities.

Progression of Plan of Care With Patient Improvement

Physical therapists provide higher-level activities as patients improve in their physical functioning. In patients with more than 1 six-hour block of PT, during the initial 6-hour block of session time patients spent up to 5.6% of their session time in bed mobility and up to 6.2% of their session time in sitting activity. Advanced gait activities comprised up to 5.9% of session time. During the final 6-hour block, when patients might be expected to have improved their physical abilities, patients spent up to 3.5% of their session time in bed mobility and up to 3.1% of their session time in sitting activity. Advanced gait activities comprised up to 10.7% of session time.

Progression to Community Mobility Activities

Time spent in community mobility increased across the time blocks regardless of the admission locomotion function. The percentage of time spent in community mobility during the final 6-hour block of therapy, however, was not greater than 5.2% for any group of patients, and as few as 14.3% of patients (those with admission FIM locomotion scores of 1 or 2 receiving 4 six-hour blocks of therapy) participated in community mobility activities during the final 6-hour block of therapy sessions.

Table 4: Characteristics of PT Sessions for Patients With 3 Six-Hour Blocks of PT

Activity*	1 Block		2 Blocks		3 Blocks	
	% Patients†	Mean % Time‡ (95% CI)	% Patients†	Mean % Time‡ (95% CI)	% Patients†	Mean % Time‡ (95% CI)
Admission locomotion 1 or 2 (n=123)						
Prefunctional	93.5	20.2 (17.9–22.5)	92.7	21.5 (19.0–24.1)	95.9	25.2 (22.3–28.0)
Bed mobility	70.7	5.4 (4.2–6.6)	61.8	4.0 (3.1–5.0)	50.4	3.0 (2.1–4.0)
Sitting	4.0	4.2 (2.9–5.6)	48.0	4.3 (3.1–6.0)	50.4	3.0 (2.1–4.0)
Transfers	95.1	14.1 (12.5–15.7)	89.4	13.1 (11.3–14.9)	85.4	11.5 (9.0–13.9)
Sit to stand	87.0	9.4 (8.1–10.7)	87.8	7.5 (6.5–8.4)	75.6	5.4 (4.2–6.7)
Wheelchair	57.7	3.4 (2.6–4.2)	42.3	2.2 (1.5–2.9)	31.7	2.0 (1.2–2.7)
Pregait	84.6	11.2 (9.6–12.8)	82.9	9.6 (8.0–11.2)	70.7	6.9 (5.7–8.2)
Gait	92.7	29.5 (26.6–32.3)	95.1	36.1 (33.1–39.1)	96.7	38.3 (35.4–41.2)
Advanced gait	17.1	1.1 (0.6–1.6)	34.4	2.8 (1.9–3.7)	96.7	6.5 (5.0–8.0)
Community mobility	6.5	0.6 (0.1–1.0)	8.1	0.5 (0.2–0.8)	19.5	1.7 (0.5–2.9)
Using cane	52.0	NA	65.9	NA	68.3	NA
Using ankle-foot orthosis	43.1	NA	44.7	NA	100.0	NA
Admission locomotion ≥3 (n=12)						
Prefunctional	91.7	23.4 (14.7–32.1)	91.7	21.1 (13.7–28.4)	100.0	31.3 (23.4–39.3)
Bed mobility	41.7	0.9 (0.1–1.6)	8.3	0.2 (−0.3 to 0.8)	25.0	0.6 (−0.2 to 1.4)
Sitting	41.7	2.9 (−1.5 to 7.3)	8.3	1.0 (−1.2 to 3.2)	25.0	0.8 (−0.2 to 1.9)
Transfers	83.3	6.1 (2.9–9.4)	91.7	8.0 (3.9–12.1)	83.3	4.2 (2.1–6.4)
Sit to stand	58.3	3.8 (0.4–7.3)	41.7	2.2 (0.4–4.0)	25.0	0.8 (−0.3 to 1.9)
Wheelchair	50.0	2.1 (0.4–3.9)	8.3	0.1 (−0.1 to 0.4)	25.0	0.7 (−0.2 to 1.5)
Pregait	83.3	14.3 (7.9–20.8)	83.3	6.2 (2.5–10.0)	58.3	4.8 (0.4–9.2)
Gait	100.0	45.0 (34.7–55.3)	100.0	54.3 (45.5–63.2)	100.0	45.2 (35.1–55.2)
Advanced gait	25.0	1.4 (−0.3 to 3.1)	66.7	5.9 (2.0–9.8)	66.7	7.0 (2.4–11.5)
Community mobility	0.0	0.0	16.7	0.9 (−0.6 to 2.5)	66.7	4.6 (2.0–7.1)
Using cane	50.0	NA	58.3	NA	66.7	NA
Using ankle-foot orthosis	25.0	NA	33.3	NA	100.0	NA

*Activities reported as percentage of time spent outside of examination and evaluation during the block.
†Percentage of patients receiving this activity during the 6-hour block.
‡Mean percentage of total time across patients spent in the activity during the 6-hour block.

Outcomes

Patients who had admission FIM locomotion scores of 1 might be considered to be at similar functional levels in terms of walking ability at admission. Based on the notion that plans of care reflect patients' ability levels, one might expect sessions to be somewhat similar in content during the first 3 hours of therapy. However, patients who had FIM locomotion scores of 1 at admission and 4 or greater at discharge spent 32.9% of their PT session time in gait during the first 3 hours of therapy, whereas patients with a FIM locomotion score of 1 at admission and a score less than 4 at discharge spent 12.7% of session time in gait activities (table 6). Similarly, patients with locomotion FIM scores of 4 or greater at discharge spent 7.2% of session time in bed mobility, 5.4% of session time in sitting activities, and 13.8% of session time in transfer activities. Patients with discharge FIM locomotion scores of less than 4 spent 8.9% of session time in bed mobility, 8.6% of session time in sitting activities, and 18.2% of session time in transfer activities.

DISCUSSION

Recent guidelines and reviews recommend that task-specific training be used in PT for people poststroke. However, to date, it has not been possible to determine what specific PT treatment approaches are used in stroke rehabilitation and how therapists adapt their treatments. The PSROP provides among the largest and most detailed explorations of PT in stroke rehabilitation. In general, it appears that the characteristics of PT treatments observed in this study are consistent with the use of a task-based approach in several ways that are outlined below. The 1 area of inconsistency with this approach is the lack of attention to the environmental context of training.

One of the most striking findings of this study is the strong focus that physical therapists have on gait training, which is consistent with the widely accepted principle of specificity of training. This principle has been confirmed in other studies, particular in the trial by Kwakkel et al,[27] which found that therapy focused on the lower limb resulted in greater improvements in walking ability whereas therapy focused on the upper limb resulted in improved dexterity, and in a recent systematic review of stroke studies.[6] The current study clearly found that physical therapists spend most of their time on gait retraining. Even among people with the most limited walking ability (ie, admission FIM locomotion score of 1), most were working on gait, and a large proportion of PT time was spent on this activity. The emphasis on gait training also occurs at the very beginning of rehabilitation; this focus is evident in the first treatment block and continues throughout the course of rehabilitation. This finding also is consistent with the work of Bode et al,[11] which found that physical therapists spend most of their time on functional rather then impairment-focused activities.

Despite the strong emphasis on gait training, there was also evidence that therapists used an individualized approach to rehabilitation (ie, the tasks were selected at the appropriate level for a patient's ability). This was seen as patients with higher functional abilities performed more advanced activities, and vice-versa. Again, this finding is consistent with Bode's recent work,[11] which found that physical therapists spent more

Table 5: Characteristics of PT Sessions for Patients With 4 Six-hour Blocks of PT

Activity*	1 Block		2 Blocks		3 Blocks		4 Blocks	
	% Patients†	Mean % Time‡ (95% CI)	% Patients†	Mean % Time‡ (95% CI)	% Patients†	Mean % Time‡ (95% CI)	% Patients†	Mean % Time‡ (95% CI)
Admission locomotion score of 1 or 2 (n=70)								
Prefunctional	90.0	18.4 (15.2–21.7)	84.3	17.1 (13.9–20.4)	88.6	18.3 (14.7–21.8)	88.6	20.6 (17.1–24.0)
Bed mobility	71.4	5.6 (4.3–7.0)	57.1	3.7 (2.6–4.8)	57.1	3.7 (2.4–4.9)	51.4	3.5 (2.1–4.8)
Sitting	57.1	6.2 (4.1–8.3)	45.7	4.0 (2.3–5.7)	37.1	3.1 (1.7–4.6)	32.9	2.3 (1.3–3.2)
Transfers	94.3	15.2 (13.0–17.4)	91.4	12.7 (10.6–14.7)	85.7	10.9 (8.6–13.1)	87.1	13.2 (10.1–16.3)
Sit to stand	87.1	10.2 (8.4–11.9)	84.3	8.9 (7.1–10.7)	82.9	7.9 (6.2–9.6)	77.1	6.4 (4.9–7.8)
Wheelchair	58.6	4.7 (3.1–6.3)	51.4	4.3 (2.8–5.8)	45.7	3.1 (2.1–4.2)	41.4	2.2 (1.3–3.2)
Pregait	91.4	13.1 (10.9–15.4)	87.1	12.7 (10.4–15.1)	81.4	11.2 (8.7–13.7)	78.6	7.8 (5.9–9.7)
Gait	91.4	25.5 (22.1–28.9)	95.7	33.4 (29.6–37.2)	95.7	35.2 (31.2–39.2)	97.1	35.0 (31.3–38.8)
Advanced gait	8.6	0.3 (0.1–0.6)	32.9	2.3 (1.3–3.3)	52.9	4.8 (3.0–6.7)	60.0	7.7 (5.1–10.3)
Community mobility	2.9	0.1 (−0.1 to 0.3)	7.1	0.5 (−0.1 to 1.1)	15.7	1.6 (0.3–3.0)	14.3	1.2 (0.4–2.0)
Using cane	60.0	NA	65.7	NA	67.1	NA	68.6	NA
Using ankle-foot orthosis	47.1	NA	44.3	NA	45.7	NA	100.0	NA

*Activities reported as percentage of time spent outside of examination and evaluation during the block.
†Percentage of patients receiving this activity during the 6-hour block.
‡Mean percentage of total time across patients spent in the activity during the 6-hour block.

time on functional activities with less-impaired people. There was also clear evidence that therapists ensured a progression of training (ie, as the patient improves, tasks become progressively more challenging). An increase in advanced activities such as advanced gait and a decrease in lower-level activities such as bed mobility occurred over time.

One finding of concern was that even in the final week of rehabilitation and in higher-functioning patients, only a small proportion of PT time was spent on community mobility. This study found that across all groups, most people are discharged from stroke rehabilitation with no community mobility training. This was a particularly surprising finding because the vast majority (>80%) of patients were discharged directly to their homes after rehabilitation. The small amount of time devoted to community-based training was not expected, given the growing body of research that indicates that the environment influences the difficulty of mobility tasks.[28,29] The findings about the impact of the environment on task difficulty suggest that people need practice in community environments before they can safely and independently function in that setting. The lack of community mobility preparation also ignores expressed priorities of stroke survivors. In a recent survey, community ambulation was considered to be important or essential by 93% of stroke survivors.[30]

There are many potential reasons why patients might not be receiving community mobility practice. One reason could be the significant reduction in length of stay that has occurred over the past several decades in both acute care and rehabilitation.[31,32] It is possible that a result of reduced time in rehabilitation is that therapists focus on achieving basic daily activities but do not have time to train people in more advanced community-based tasks. Another possible contributor to the focus on more basic activities could be the use of the FIM instrument itself. Rehabilitation hospitals use changes in the FIM as quality indicators of success in rehabilitation. However, the FIM was designed to measure only basic activities of daily living and, as such, does not capture patients' performances in more advanced participation activities.

The lack of community-based preparation before discharge from a rehabilitation hospital places a large burden on home- and outpatient-based services. However, the amount of therapy time that patients receive from these services also is limited and has decreased in recent years.[33] Recent studies found that important declines in function and quality of life occur after discharge from inpatient stroke rehabilitation.[34,35] In particular, Paolucci et al[34] found that mobility declined in over 40% of people on their return home. These findings suggest that in the transition from inpatient rehabilitation to home, a significant number of people experience difficulties. It is possible that a lack of community-based practice before discharge could contribute to some of these problems.

Some limitations of this work include the fact that there were no data available for follow-up after discharge. In addition, the only functional outcome measure is the FIM, a measure of basic activities of daily living. However, the aim of this study was to explore functional changes that take place within inpatient rehabilitation, and this study has numerous strengths in this area. This study included a large number of patients from multiple sites that were geographically distributed around the United States. This increases potential accuracy and generalizability of these findings. Another important feature of this study was the creation of a detailed taxonomy of activities and interventions. This allowed us to have a much more precise understanding of the specific therapeutic treatments that patients received throughout their rehabilitation. Finally, this study involved clinicians from the participating centers during

Table 6: Discharge FIM Locomotion Scores and Percentage of Time Spent in Activities During the First 3 Hours of PT for Patients With 3 Six-Hour Blocks of PT and Admission FIM Locomotion Scores of 1 (n=66)

Activity	Discharge FIM Locomotion Item Score	
	<4	≥4
Prefunctional, mean % time (95% CI)	17.7 (11.2–24.2)	15.4 (10.9–19.8)
Bed mobility, mean % time (95% CI)	8.9 (3.2–14.6)	7.2 (4.3–10.1)
Sitting, mean % time (95% CI)	8.6 (2.9–14.3)	5.4 (2.1–8.8)
Transfer, mean % time (95% CI)	18.2 (14.2–22.2)	13.8 (10.9–16.7)
Sit to stand, mean % time (95% CI)	14.5 (10.3–18.7)	9.6 (6.9–12.2)
Wheelchair, mean % time (95% CI)	5.3 (2.1–8.4)	4.0 (1.3–6.7)
Pregait, mean % time (95% CI)	11.5 (7.4–15.6)	11.1 (7.5–14.7)
Gait, mean % time (95% CI)	12.7 (7.4–15.6)	32.9 (27.3–38.5)
Advanced gait, mean % time (95% CI)	0.0	0.0
Community mobility, mean % time (95% CI)	0.8 (−0.4 to 2.0)	0.0
Using cane (% of patients)	26.9	30.0
Using ankle-foot orthosis (% of patients)	38.5	60.0

all stages of the project. This helped to increase the validity of the study design and integrity of the results.

Additional research questions are worthy of further exploration using this dataset. These include, for example, looking at treatment approaches and functional outcomes of people who used primarily wheelchairs for their locomotion and exploring how particular risk factors associated with poorer functional outcomes after rehabilitation, such as bowel and bladder incontinence or depression, influenced the physical therapists' selection of therapeutic activities.

CONCLUSIONS

Overall, this study found that people in poststroke rehabilitation are receiving therapy that is generally consistent with a task-based training approach. Physical therapists focus their treatment strongly on the task of gait. Therapists adapt their training for people with more impaired walking ability and as patients progress through the rehabilitation process. However, a small percentage of time during inpatient therapy is spent on advanced mobility activities, and many people do not practice walking in the community with a physical therapist before discharge home. This is a concern, given evidence supporting the influence that the environment has on task difficulty and the challenges that patients face when they return to their homes and communities from an inpatient setting.

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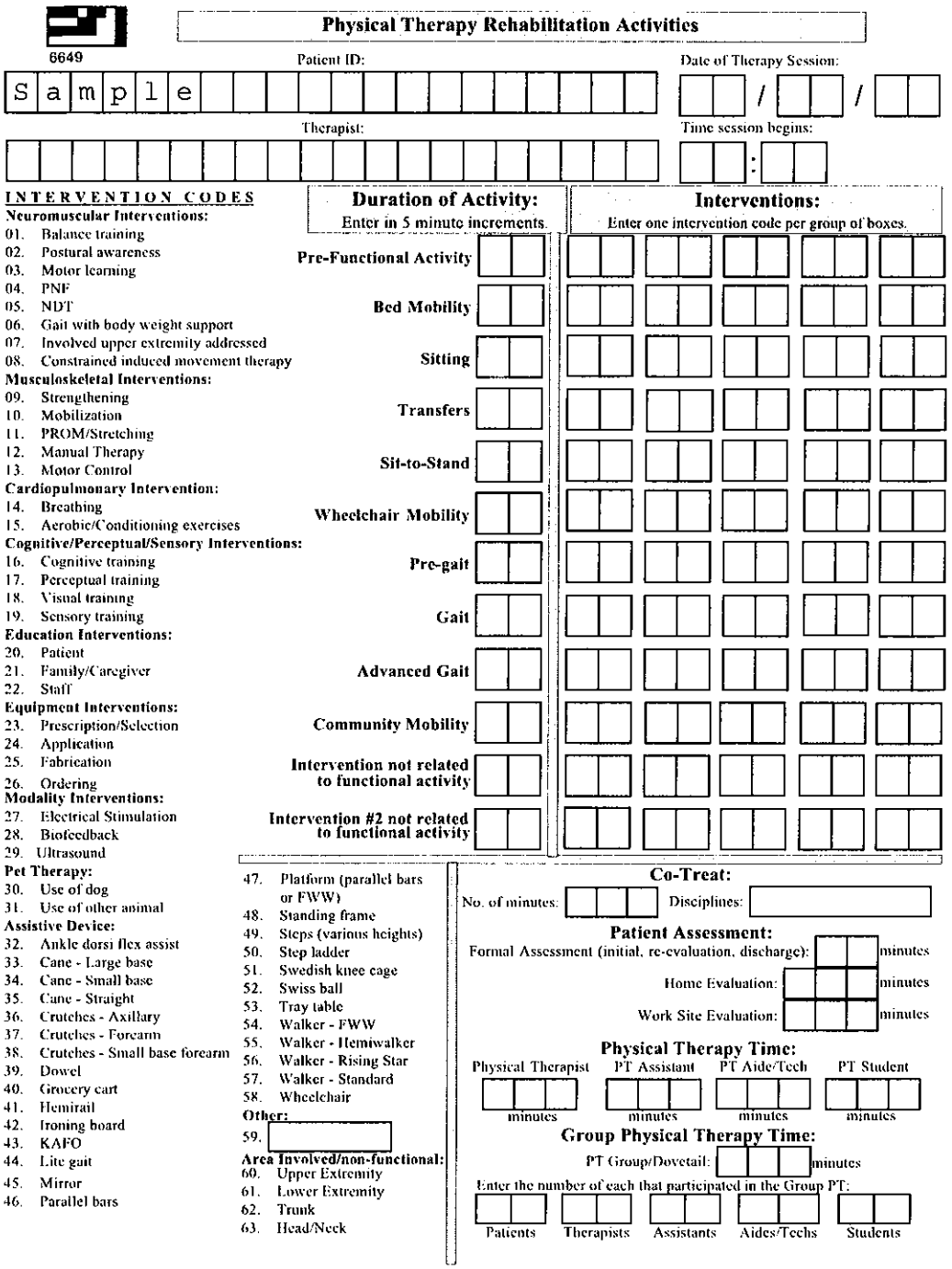
APPENDIX 1: PT INTERVENTION DOCUMENTATION FORM



Physical Therapy Rehabilitation Activities

6649

Patient ID: Sample

Date of Therapy Session: / /

Therapist:

Time session begins: :

INTERVENTION CODES

Neuromuscular Interventions:
01. Balance training
02. Postural awareness
03. Motor learning
04. PNF
05. NDT
06. Gait with body weight support
07. Involved upper extremity addressed
08. Constrained induced movement therapy

Musculoskeletal Interventions:
09. Strengthening
10. Mobilization
11. PROM/Stretching
12. Manual Therapy
13. Motor Control

Cardiopulmonary Intervention:
14. Breathing
15. Aerobic/Conditioning exercises

Cognitive/Perceptual/Sensory Interventions:
16. Cognitive training
17. Perceptual training
18. Visual training
19. Sensory training

Education Interventions:
20. Patient
21. Family/Caregiver
22. Staff

Equipment Interventions:
23. Prescription/Selection
24. Application
25. Fabrication
26. Ordering

Modality Interventions:
27. Electrical Stimulation
28. Biofeedback
29. Ultrasound

Pet Therapy:
30. Use of dog
31. Use of other animal

Assistive Device:
32. Ankle dorsi flex assist
33. Cane - Large base
34. Cane - Small base
35. Cane - Straight
36. Crutches - Axillary
37. Crutches - Forearm
38. Crutches - Small base forearm
39. Dowel
40. Grocery cart
41. Hemirail
42. Ironing board
43. KAFO
44. Lite gait
45. Mirror
46. Parallel bars
47. Platform (parallel bars or FWW)
48. Standing frame
49. Steps (various heights)
50. Step ladder
51. Swedish knee cage
52. Swiss ball
53. Tray table
54. Walker - FWW
55. Walker - Hemiwalker
56. Walker - Rising Star
57. Walker - Standard
58. Wheelchair

Other:
59.

Area Involved/non-functional:
60. Upper Extremity
61. Lower Extremity
62. Trunk
63. Head/Neck

	Duration of Activity: Enter in 5 minute increments.	Interventions: Enter one intervention code per group of boxes.
Pre-Functional Activity		
Bed Mobility		
Sitting		
Transfers		
Sit-to-Stand		
Wheelchair Mobility		
Pre-gait		
Gait		
Advanced Gait		
Community Mobility		
Intervention not related to functional activity		
Intervention #2 not related to functional activity		

Co-Treat:
No. of minutes: Disciplines:

Patient Assessment:
Formal Assessment (initial, re-evaluation, discharge): minutes
Home Evaluation: minutes
Work Site Evaluation: minutes

Physical Therapy Time:

Physical Therapist	PT Assistant	PT Aide/Tech	PT Student
minutes	minutes	minutes	minutes

Group Physical Therapy Time:
PT Group/Dovetail: minutes
Enter the number of each that participated in the Group PT:

Patients	Therapists	Assistants	Aides/Techs	Students

Abbreviations: FWW, front-wheel walker; KAFO, knee-ankle-foot orthosis; NDT, neurodevelopmental treatment; PNF, proprioceptive neuromuscular fasciculation; PROM, passive range of motion.

APPENDIX 2: FIM LOCOMOTION ITEM SCALE

Locomotion/walk: Includes walking, once in a standing position, on a level surface.

No Helper	
7	Complete independence: subject walks a minimum of 150ft (50m) without assistive devices. Performs safely.
6	Modified independence: subject walks a minimum of 150ft (50m) but uses a brace (orthosis) or prosthesis on leg, special adaptive shoes, cane, crutches, or walkerette; takes more than reasonable time or there are safety considerations.
5	Exception (household ambulation): subject walks only short distances (a minimum of 50ft [17m]) with or without a device. Takes more than reasonable time or there are safety considerations.
Helper	
5	Supervision: subject requires standby supervision, cuing, or coaxing to go a minimum of 150ft (50m).
4	Minimal contact assistance: subject performs 75% or more of locomotion effort to go a minimum of 150ft (50m).
3	Moderate assistance: Subject performs 50% to 74% of locomotion effort to go a minimum of 150ft (50m).
2	Maximal assistance: Subject performs 25% to 49% of locomotion effort to go a minimum of 50ft (17m). Requires assistance of one person only.
1	Total assistance: subject performs less than 25% of effort, requires assistance of 2 people, or does not walk a minimum of 50ft (17m).

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ORIGINAL ARTICLE

Characterizing Occupational Therapy Practice in Stroke Rehabilitation

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ABSTRACT. Richards LG, Latham NK, Jette DU, Rosenberg L, Smout RJ, DeJong G. Characterizing occupational therapy practice in stroke rehabilitation. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S51-60.

Objectives: To describe how occupational therapy (OT) activities during stroke inpatient rehabilitation vary by admission functional status and over time and how time spent in these various activities relates to functional status at discharge.

Design: Observational cohort study.

Setting: Six inpatient rehabilitation hospitals in the United States.

Participants: People (N=713) receiving 4 to 19 hours of poststroke OT.

Interventions: Not applicable.

Main Outcome Measures: Patients were categorized by number of 4-hour blocks of OT received and by admission upper-extremity (UE) dressing score on the FIM instrument. In each group, the percentage of time spent in 16 activities and the percentage of patients who received each activity were calculated. The amount of time in activities was compared for those patients scoring 1 or 2 at admission who achieved at least a level of supervision for UE dressing (a score of ≥5) using Wilcoxon 2-sample tests.

Results: The majority of OT time was spent in impairment-focused activities (37.5%) or training basic activities of daily living (31.9%). Treatment progressed to more advanced activities over time (eg, less bed mobility, more home management), yet little time was spent on community integration or leisure activities and with very few patients. Successful patients received more higher-level activities, whereas unsuccessful patients received larger amounts of basic-level activities.

Conclusions: OT activities focused on a combination of remediating impairments and retraining specific functional tasks, at the ability level of each individual patient, and provided higher-level activities as patients improved their function. More time in higher-level activities was related to greater success in rehabilitation. However, higher-level activities remain the least common activities provided during inpatient rehabilitation.

Key Words: Activities of daily living; Clinical practice patterns; Cerebrovascular accident; Occupational therapy; Rehabilitation.

A DETAILED LITERATURE REVIEW substantiating the need to examine multidimensional rehabilitation processes to improve outcomes for specific types of patients is presented elsewhere.[1] Also described elsewhere is an introduction on where this study's research methodology fits into the pantheon of biomedical and clinical research methodology.[2]

Occupational therapists play a key role in poststroke rehabilitation. People with stroke make up the most common diagnostic group served by occupational therapists.[3-5] However, precise descriptions of activities occupational therapists provide to patients undergoing inpatient stroke rehabilitation are lacking. The Occupational Therapy Practice Framework[6] asserts that occupational therapists should address ability to participate in activities in a variety of life roles. The process for facilitating participation in stroke rehabilitation can include a mixture of remediation, compensatory techniques, and preventative intervention. Knowledge of which occupational therapy (OT) process combinations are best for facilitating successful rehabilitation outcomes is not known.

Several recent systematic reviews suggest that OT improves the performance of some functional tasks and reduces impairments after a stroke.[7-9] A few observational studies describe the nature of OT interventions currently being used for stroke rehabilitation. For the most part, such studies have been conducted in countries outside the United States,[10-12] have described treatment only in terms of duration or frequency,[10,13,14] or have involved a limited number of patients.[11,12] Keren et al[15] found that OT provided more intensely was associated with more cognitive improvement and higher scores on the cognitive domains of the FIM but did not describe the actual activities provided by these occupational therapists. The National Board for Certification in Occupational Therapy Practice Analysis reported the frequency with which entry-level practitioners used specific interventions but did not break these down by patient condition and only surveyed occupational therapists within the first 3 years of their practices.[5]

Recently, only 2 studies have examined in detail the content of OT in inpatient stroke rehabilitation. Bode et al[16] surveyed the content of therapy for 177 patients with stroke undergoing 2 to 5 weeks of inpatient stroke rehabilitation across 8 acute and 5 subacute settings in the United States between 1993 and 2000. Health care providers in these settings recorded time spent across 5 activity categories (evaluation and screening, activities of daily living [ADLs] and instrumental activities of daily living [IADLs], interventions for performance skills or

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body structure and function impairments, discharge planning, or case management) in 15-minute increments. They found that occupational therapists spent most of their time providing interventions that addressed performance skills or body structure and function impairments, such as motor rehabilitation, cognitive retraining, or therapeutic equipment.

As part of the Post-Stroke Rehabilitation Outcomes Project (PSROP), members of our group created a taxonomy of activities used in OT.[17] This taxonomy provides details about treatments and therapeutic activities that therapists used throughout the rehabilitation stay. We recently reported on the percentage of time in OT that 954 patients spent in the 16 OT activities during inpatient poststroke rehabilitation.[18] Although we organized our activities somewhat differently from Bode et al,[16] we also found that occupational therapists spent almost half of the therapy time using activities that directly targeted remediating performance skills or body structure and function impairments (ie, upper-extremity [UE] control, sitting balance, bed mobility, wheelchair, prefunctional, transfers). The second most common set of activities provided was the practice of basic ADLs (BADLs). A variety of intervention techniques were associated with each activity.

Our previous report described OT activities provided for patients undergoing inpatient stroke rehabilitation without concern for the functional levels of patients. However, occupational therapists most likely base intervention selections on the impairment and activity limitations of each patient, as well as the amount of therapy time that will be tolerated by each patient. In addition, it is likely that the types of activities and interventions that are provided vary across a patient's rehabilitation stay. These ideas receive support from the Bode[16] study, in which the amount of time spent in ADLs and IADLs versus impairment-focused activities varied somewhat with length of stay and whether a patient was more or less impaired. Therefore, in this report, we provide a more detailed description of OT for people undergoing stroke rehabilitation by classifying patients on the basis of amount of OT received and amount of limitation exhibited in ADL performance at admission. We then describe OT activities that therapists provided as interventions across the rehabilitation episode.

METHODS

The methodology governing the full PSROP, provided in this supplement by Gassaway et al,[19] presents a detailed description of the larger study's participating facilities, patient selection criteria, data collection instruments including their validity and reliability, and a detailed description of the project's final study group. The methodology is summarized in Maulden et al.[20] The institutional review boards at Boston University and at each participating inpatient rehabilitation facility (IRF) approved the study.

Patients in the OT Subset

We examined a subset of the PSROP U.S. database that received at least 1 OT session during rehabilitation as documented on project point-of-care OT intervention documentation forms. OT sessions were documented for 1096 U.S. patients (94% of the 1161-subject U.S. sample).

The next step was to identify the amount of OT services that patients received. The amount of OT received was divided into 4-hour blocks. Those 713 patients who had at least 1 four-hour block and less than 5 four-hour blocks of therapy were selected for analysis in this report. We chose this group of patients because our data showed that patients with less or more time in rehabilitation may have had important differences in illness severity and function from the group receiving 3 to 19 hours of therapy.

Instrumentation

The OT intervention documentation form (appendix 1) developed for the PSROP included a taxonomy of information such as targeted activity area, interventions used by the clinician within each activity, and duration of each activity, measured in 5-minute increments. Activity categories included prefunctional, bed mobility, sitting balance, UE control, transfers, wheelchair management, bathing, grooming, dressing, toileting, feeding, functional mobility, home management, community integration, and leisure. Definitions for the activities and interventions contained on the OT intervention documentation form were provided to practicing clinicians and are available on request. Additional information, such as whether the session was individual or group, time spent in evaluation and planning, and potentially influential professional discussion of the patient among colleagues, was also obtained. One OT intervention documentation form was completed for each OT session a patient received during his/her inpatient rehabilitation stay.

A lead occupational therapist from each IRF participated in a train-the-trainer teleconference to learn how to use and teach others to use the OT intervention documentation form. After the teleconference, the lead occupational therapists trained colleagues in their respective IRFs.

Each site incorporated auditing of intervention documentation form use into routine site practices. Typically, the lead occupational therapists observed a patient session and completed a separate intervention documentation form based on what was observed. The therapist providing the session completed a form as per protocol. The lead therapist reviewed and discussed differences in completion with the practicing therapist.

Face validity was built into the intervention documentation forms as they were developed and used by IRF therapists as described above. Predictive validity was assessed by showing significant effects of OT interventions (and other therapy interventions) on outcomes.[21-23] For example, the amount of variation explained in discharge FIM score, controlling for patient characteristics (including admission FIM score, severity of illness, and demographic factors), was 40% for moderate strokes and 45% for severe strokes. When total time per day spent on physical therapy (PT), OT, and speech-language pathology (SLP) was added, there was no increase in variation explained for discharge FIM score, consistent with previous findings by Bode[16] However, when time per day spent in specific PT, OT, and SLP activities was added, the amount of variation explained increased to 52% for moderate strokes and 68% for severe strokes, adding 12% to 23% explanation of variation, respectively, in discharge FIM scores.

Functional performance for each study patient at admission to and discharge from inpatient rehabilitation was obtained via retrospective chart review using the study site's reporting of the FIM.[24,25] We assumed all clinicians providing FIM data within IRFs as part of standard practice were FIM credentialed; no additional documentation of FIM elements was performed for project purposes. We categorized our sample by a representative admission functional status score on the FIM. The UE dressing score was selected as our categorizing variable because dressing practice was one of the most frequently reported activities provided to this group of patients,[18] and because only 3 patients were more independent in lower extremity than UE dressing at baseline. Appendix 2 provides a description of FIM levels for the UE dressing component.

Data Analysis

Patients were divided into those who received 1, 2, 3, or 4 four-hour blocks of OT. Because data concerning activities were collected across an entire session and because OT sessions differed in length, each 4-hour block of therapy could contain a variable number of sessions. Therefore, we classified patients using the number of full sessions that would bring the therapy hours the closest to 4, 8, 12, and 16 hours of OT without including the next time block. For example, patients classified as having 1 four-hour block of therapy received between 3 and 4.75 hours of OT during their rehabilitation stay. For each group, descriptive statistics were derived to examine patients' demographics and processes of care. Then, because we believed that the content of therapy is driven by the severity of patients' deficits and activity limitations, we grouped patients by FIM UE dressing scores: 1 or 2, 3 or 4, or 5 or more.

For each OT duration (eg, number of 4-h blocks) and UE dressing FIM score group, we first determined the percentage of time spent in assessment and then determined the percentage of all nonassessment OT time across blocks and for each block of therapy spent directed to each OT activity. In addition, we examined the amount of time spent in home assessment. Second, we wanted to determine whether the amount of time spent in any of these activities was associated with better outcomes. To do this, we examined the group of patients who required the most assistance in UE dressing at the start of rehabilitation (those scoring 1 or 2 on the FIM UE dressing item). We defined attaining a level of supervision or better for UE dressing (a score of $\geq$5 on the FIM UE dressing item) at discharge as successful rehabilitation. We ran Wilcoxon nonparametric 2-sample tests comparing mean percentage time spent in each activity between those who achieved a 5 or greater on the FIM UE dressing item and those who failed to achieve such a result. Because this analysis was considered exploratory in nature, we did not control for simultaneous error rates.

RESULTS

Table 1 gives the demographic, process, and outcome variables for patients in this analysis. Generally, patients with longer durations of OT had a longer time period from onset of stroke to rehabilitation admission, a lower admission motor FIM score, and slightly lower admission cognitive FIM scores. Thus, patients with more functional deficits received more OT. Approximately the same percentage of patients in each group returned home. Patients' time in OT was divided into 4-hour blocks of therapy. Each block ranged, on average, from 223.6 to 242.1 minutes and consisted of between 5.2 and 6.8 sessions across 4 to 8 days. It appeared that occupational therapists designed therapy based more on the level of dysfunction of each patient and changed therapy across the rehabilitation episode rather than the amount of time the patient was in

Table 1: Characteristics of Patient, Process, and Outcome Variables by Amount of OT Received

PSROP Variable	No. of 4-Hour Blocks of OT			
	1 (n=188)	2 (n=209)	3 (n=175)	4 (n=141)
Patient characteristics				
Mean age (y)	67.1	68.2	66.2	66.4
Race (%)				
White	53.2	58.4	58.3	63.1
Black	26.1	25.4	24.6	20.6
Other, including Hispanic	20.7	16.2	17.1	16.3
Sex (% men)	48.4	51.2	49.7	49.7
Type of stroke (%)				
Hemorrhagic	25.5	25.8	27.4	22.0
Ischemic	74.5	74.2	72.6	78.0
Side of stroke (%)				
Left	40.4	38.8	45.1	41.8
Right	46.8	46.4	41.7	51.1
Bilateral	10.1	12.9	10.9	5.0
Unknown	2.1	2.3	1.9	2.7
Mean admission motor FIM score	45.2	40.6	38.5	36.0
Mean admission cognitive FIM score	21.7	21.5	21.3	20.2
Mean days from symptom onset to rehab admission	10.3	12.5	14.7	16.6
Process variables				
Mean length of stay	10.7	14.8	19.0	23.1
Mean total minutes of OT	291	523	759	996
Mean total no. of OT sessions	7.2	13.1	19.2	26.9
Outcome variables				
Discharge disposition (%)				
Home	79.8	80.9	75.4	80.1
Board and care (assisted living)	0.5	1.9	2.9	5.5
Skilled nursing facility	8.5	12.4	18.3	12.8
Acute care hospital (own or other facility)	9.0	2.9	0.6	0.7
Other rehabilitation facility	2.1	2.4	2.9	0.7
Mean discharge motor FIM score	63.0	63.8	61.8	60.6
Mean discharge cognitive FIM score	25.3	25.5	25.1	25.3

Abbreviation: rehab, rehabilitation.

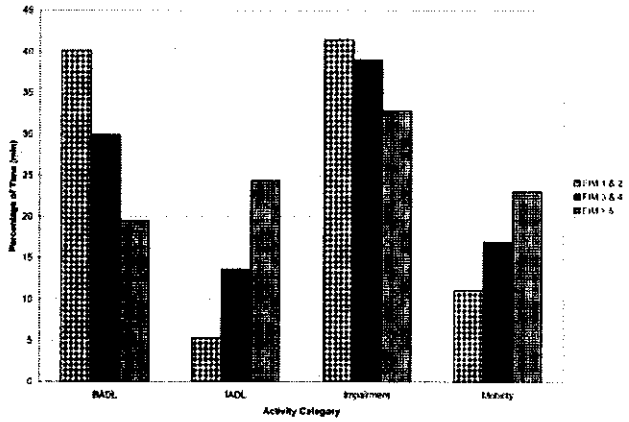

Fig 1. Amount of time spent in activity categories for patients with 1 four-hour block of therapy across admission FIM UE dressing scores.

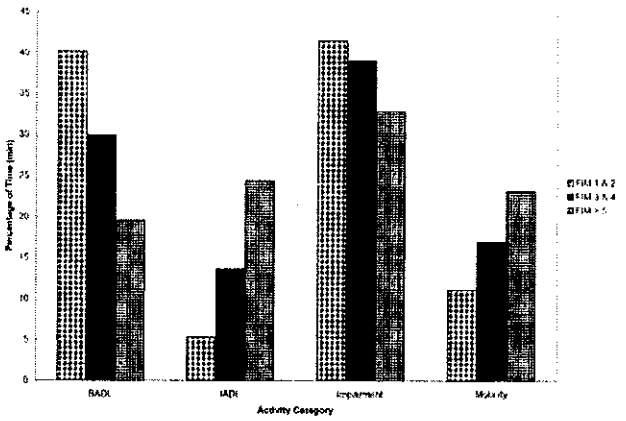

Fig 3. Amount of time spent in activity categories for patients with 3 four-hour blocks of therapy across admission FIM UE dressing scores.

rehabilitation. However, in general, occupational therapists provided each activity to a larger percentage of patients as the number of OT blocks provided increased. To understand patterns in the data, we divided activities into 4 categories: BADL training, IADL training, impairment-focused activities (those targeting performance skill or body structure and function impairments—eg, UE control or prefunctional activities), and mobility activities. Figures 1 through 4 show the pattern of time spent in each therapy across admission FIM UE dressing levels.

Occupational therapists provided both basic impairment-focused activities and BADLs to a majority (n=672) of patients. In general, impairment-focused activities were the most, and BADLs the second most, frequently provided activities (37.5% and 31.9% of therapy, respectively). Of the impairment-focused activities, the least amount of time was spent working on activities to improve sitting balance and the most time was spent providing UE control activities. In fact, UE control was the most frequently provided activity across activities (except for the 2-block, FIM 1 or 2 group). The most frequently provided BADL activity was dressing training; the least amount of time was spent in feeding.

Therapists tailored therapy to patients' levels of dysfunction in these activities. Typically, the amount of time occupational therapists spent in impairment-focused and BADL activities decreased as admission FIM UE dressing level increased, regardless of how many blocks of OT patients received.

Occupational therapists provided IADL training to 75.5% of patients. For all patient groups, the percentage of patients given IADL training and the amount of time spent in IADL training increased as FIM UE dressing level increased. Home management activities were the most frequent activities provided, but occupational therapists devoted little time to either community integration or leisure activities (<10% of time to community integration, <5% to leisure) for any of the patient groups. Occupational therapists performed few home evaluations (0%–7.9% of patients received a home evaluation, with no more than 1.8% of time spent on home evaluation), despite a large percentage of patients returning home. Sixty-nine percent of patients who were discharged home received recommendations for follow-up therapy (home health or outpatient).

Mobility training was provided to 88.4% of patients. In general, occupational therapists spent more time working on mobility skills with patients with higher FIM UE dressing

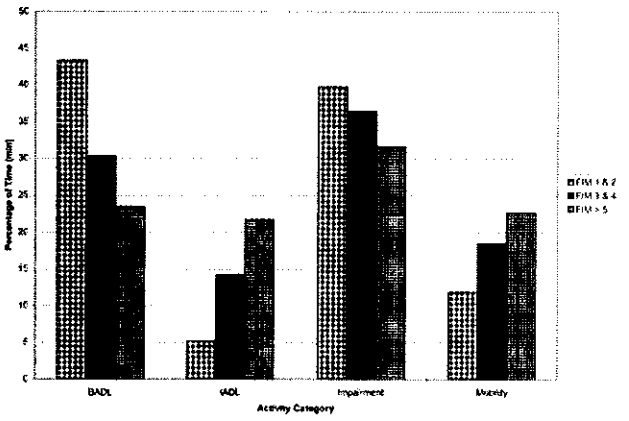

Fig 2. Amount of time spent in activity categories for patients with 2 four-hour blocks of therapy across admission FIM UE dressing scores.

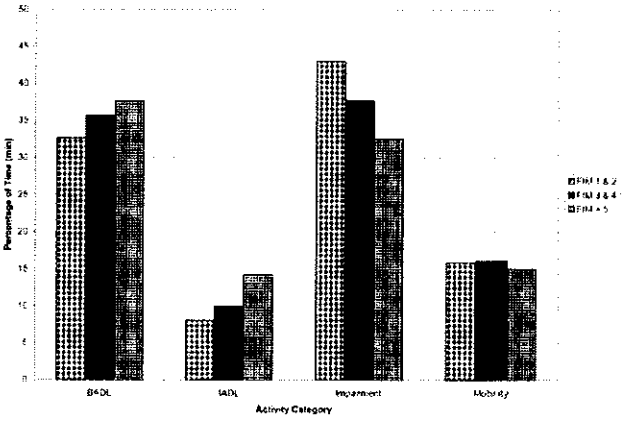

Fig 4. Amount of time spent in activity categories for patients with 4 four-hour blocks of therapy across admission FIM UE dressing scores.

scores. The pattern of time spent in each activity varied. Although transfer training was the most frequent mobility training provided for those patients with admission FIM UE dressing scores of 1 or 2, functional mobility training was the most frequently provided mobility training for most patients who had FIM UE dressing scores of 3 to 5.

We were also interested to know whether the amount of time spent in more basic activities decreased and that spent in more complex activities increased across the rehabilitation episode as patients presumably improved in function. Indeed, this was generally the case. The amount of time in the following basic activities typically decreased the longer a patient was in therapy: dressing, grooming, feeding, bed mobility, and sitting balance. More complex activities of home management, functional mobility, community integration, and leisure tended to increase the longer patients were in rehabilitation.

Relation of Activities to Outcome

One hundred fifty-two patients started rehabilitation at a dependent or maximum-assist level of UE dressing. Forty-seven achieved at least a supervised level of independence in UE dressing by discharge, and 105 did not. Table 2 describes the mean percentage of time spent in each activity for those patients with and without a successful UE dressing outcome. First, it is important to notice that although we defined success based on the UE dressing item of the FIM, all FIM item scores are lower for the nonsuccessful group than for the successful group. Those who were successful at obtaining a FIM UE dressing score of at least 5 were provided with a greater amount of time in higher-level activities such as community integration, functional mobility, home management, and leisure activities. In contrast, patients who failed to obtain a score of 5 or greater on the FIM UE dressing item received more OT directed toward the lower-level activities of wheelchair management, sitting balance, grooming, and feeding. The percentage of time spent on toileting, transfers, UE control, bathing, bed mobility, and dressing did not differentiate those who succeeded from those who failed to obtain at least a supervised level in UE dressing activities.

Table 2: Mean Percentage of Time Spent on Therapeutic Activities by UE Dressing Outcome

PSROP Variable (mean % of time)	Achieved ≥5 on FIM UE Dressing Item at Discharge		Wilcoxon 2-Sample Test	
	Yes	No	*t*	*P*
Formal assessment	8.2	6.8	4014.5	.090
Home assessment	0.6	1.0	3582.0	.882
Bathing	4.0	5.1	3302.5	.217
Bed mobility	1.2	1.8	3423.5	.462
Feeding	2.1	4.2	3110.0	.032
Dressing	19.5	19.7	3577.5	.943
Functional mobility	6.5	2.7	4281.5	.005
Grooming	5.1	9.0	2887.0	.005
Leisure	3.0	1.4	4015.0	.029
Toileting	2.8	2.6	3681.0	.718
Transfers	6.7	6.8	3713.0	.635
Sitting balance	2.6	6.1	2912.0	.005
UE control	25.6	23.6	3889.5	.241
Wheelchair management	0.5	1.5	3123.5	.016
Prefunctional	12.8	12.7	3651.0	.825
Home management	4.9	1.6	4357.0	.000
Community integration	2.7	0.8	4034.5	.013

NOTE. Patients at a dependent (FIM score, 1) or maximum-assistance (FIM score, 2) level in UE dressing at admission. Outcome: attain at least a supervised level of function in UE dressing at discharge.

DISCUSSION

According to the Occupational Therapy Practice Framework,[6] occupational therapists should assist patients in regaining the ability to complete activities across multiple life roles. These activities include BADLs, home management, work or school activities, and leisure or recreation. Facilitating increased independence and participation can be achieved either by modifying tasks and adapting environments, by decreasing impairment in body structures and functions, or a combination of approaches. Therapists are encouraged to tailor therapy to the needs of patients and the likelihood of goal attainment within the amount of therapy time available. Therefore, to expand our original report in which we catalogued time spent in OT activities across all PSROP patients with stroke, in this report we analyzed time spent in these activities based on the amount of disability exhibited by each patient (represented by the FIM UE dressing item score) and the amount of OT the patient received. In addition, it is expected that therapy should change as patients gain in skill. Hence, we also analyzed how the amount of time spent in OT activities changed across the rehabilitation episode.

Do Occupational Therapists Use a Strategy of Task Training or Restoration of Body Structure and Function?

Our data show that occupational therapists frequently use a combination of approaches. For all but 1 patient group, the most common group of activities provided to these patients undergoing inpatient stroke rehabilitation was impairment-focused activities, followed by BADL training. This finding is similar to that of Bode et al,[16] who reported that occupational therapists spent more time providing impairment-focused than functional activities to most of their patients. The 2 activities that occupational therapists spent the most time delivering were UE control and dressing activities. Thus, it appears that occupational therapists value the practice of actual daily tasks but also view the motor impairments caused by stroke to be a significant problem that needs to be addressed in therapy.

Do Occupational Therapists Address Activities Across Life Roles?

Our data indicate that the kinds of activities addressed in OT during inpatient stroke rehabilitation were restricted. Basic self-care activities were provided to nearly all patients, with a large percentage of time spent in these activities. IADLs involved in home management, however, were primarily provided to those patients with greater function at admission, probably because therapy time for patients at a lower functional level was spent on more basic activities. In addition, very little time was spent providing leisure activities to a very small number of patients. What is more disconcerting is how little attention is paid to community integration activities, which in our study was defined with a heavy emphasis on community mobility. Difficulty being mobile in the community (getting into and out of a car, driving, using public transportation) severely restricts participation in activities outside the home and precludes many recreation and social activities. These data underscore the need for adequate community-based therapy services to facilitate independence in community participation—unfortunately at a time when the amount of therapy

patients receive from outpatient or home health services has decreased dramatically.[26]

The lack of attention to these higher-level activities may stem from several sources. One possibility is short rehabilitation stays combined with the view that the ability to perform more basic activities is a precursor to training higher-level activities. Such a view may not be unfounded. The belief that improving basic motor skills will lead to increased function is inherent to motor rehabilitation, and several studies have shown that improvements in motor skills is associated with increases in functional ability.[27,28] In addition, inability to complete basic self-care activities independently or at least with minimal assistance often determines whether patients are discharged to the community, where they have the opportunity to engage in higher-level activities. It is possible that were rehabilitation stays longer, therapists would provide more advanced activities later on in the rehabilitation episode. This idea receives some support from our data, which show that more patients were provided with and increased time was spent in these activities as the rehabilitation episode progressed. Another possible contributor to the focus on more basic activities could be the use of the FIM instrument itself. Rehabilitation hospitals use changes in FIM scores as quality indicators of success in rehabilitation. However, the FIM was designed only to measure BADLs and, as such, does not capture patients' performances in more advanced participation activities.

The small amount of leisure training provided by the occupational therapists in our study may reflect the fact that the therapists worked on health care teams that also included recreation therapists. Therefore, despite the OT profession endorsing leisure activities as falling within the domain of OT, leisure training and counseling on these teams may have been the province of recreation therapists.

Do Occupational Therapists Tailor Therapy Based on Patient Disability?

We found partial evidence to suggest that occupational therapists tailored therapy based on patient functional level, both at admission and as patients recovered. For example, less time was spent in low-level activities (eg, grooming, sitting balance, bed mobility) with those patients scoring at a FIM UE dressing level 5 or above compared with those scoring at levels 1 or 2, whereas the amount of time spent in the higher activities of functional mobility and home management was greater for the former group of patients. A larger amount of time was spent on higher-level activities, such as functional mobility and home management and less time on more basic activities (eg, sitting balance) later in the rehabilitation episode. Bode et al[16] also found that for some groups of patients, occupational therapists tailored their activities based on patient disability. For example, for patients with 2-week rehabilitation durations, occupational therapists provided more functional activities to those with less disability compared with more impairment in the last week of rehabilitation, whereas the reverse was seen for those with 5-week stays. However, because they did not break down their functional category into BADLs, IADLs, and mobility, nor into higher- or lower-level activities within those categories, direct comparisons between their study and ours is not possible.

However, the amount of time spent in dressing and UE control activities remained substantial. This may reflect the breadth of those categories. Dressing tasks, for example, range from the simple—putting on a T-shirt—to the complicated—donning of a brassiere or tying shoelaces. UE control ranges from simple 1-joint proximal movements to tasks such as piano playing, which requires exquisite fine motor control. In addition, the affected UE poststroke has been particularly resistant to recovery to a functional capacity, most likely because of the level of coordination required to have a functional hand.[29] As UE function improved, BADL training may have progressed from compensatory training to a more remedial approach in which emerging UE motor skills were incorporated into BADLs. Therefore, it is likely that patients experienced a continued need for UE training and BADL training throughout the rehabilitation episode. Because we did not collect data about subactivities within each BADL category (ie, putting on a T-shirt and fastening a hook closure; both were categorized as dressing yet require very differing motor skills), actual therapy differences between patients of different functional levels could not be detected by these categories.

Although we found that occupational therapists customized therapy based on patient disability, we found little evidence to suggest that therapy was tailored based on the amount of OT provided. Because most patients eventually were referred to outpatient or home health therapy, therapists in the inpatient rehabilitation setting may believe that their therapy only begins the process of facilitating independence. Therapy does not need to be limited if there is a belief that continued training will be available once a patient leaves the facility. However, this belief may be erroneous given the decreased amount of therapy time that patients receive from outpatient or home health services.[26] Although occupational therapists did not seem to alter activities provided based on amount of time available in rehabilitation, they might have altered specific methods used for training within these activities. For example, they may have provided more compensatory than remedial training when rehabilitation stays were shorter. The current data do not speak to whether such alterations in OT intervention techniques occur.

Is the Amount of Time in OT Activities Related to Functional Outcome?

The intent of rehabilitation is to promote independence in functional activities. There has been little evidence to date to guide therapists in treatment planning. However, there have been studies finding that OT can improve task performance and reduce impairments after stroke.[7-9] There is a great need to examine which aspects of OT practice are and are not effective. In this study, we examined the relation between amount of time spent in various OT activities with outcomes in UE dressing skill for those patients who were admitted to rehabilitation at a dependent or maximum-assist level of independence in UE dressing. Those patients who successfully achieved at least a supervised level of UE dressing had been provided with larger amounts of therapy directed at higher-level activities than those who were unsuccessful in achieving this level of independence. This result is similar to that found in the study by Latham et al,[21] in which more PT time in advanced gait activities was found for those patients with greater success in rehabilitation. It may be that practicing the types of motor and cognitive processing required of these higher-level activities facilitates gains in independence in other areas of daily functioning. Alternatively, it may be that those patients who were successful in rehabilitation received greater amounts of higher-level activities because they experienced more recovery and were better able to engage in such activity practice.

We were surprised that amount of time spent in dressing activities did not delineate those who were successful in UE dressing recovery from those who were not. We would have expected an increased amount of time spent in dressing activities to be associated with an item on the FIM measuring dressing ability. One possible reason that this was not so is that the activity category of dressing covers a wide range of activities, from putting on a shirt or pants to tying shoelaces. It may

be that both groups received a similar amount of dressing training but that this training emphasized different dressing activities.

We also were surprised that the most frequently provided activity was not associated with successful outcome. On average, occupational therapists spent nearly a third of their time providing UE control activities, yet this training was not associated with success in UE dressing. There are several possible reasons for this. First, it must be emphasized that our definition of success was limited solely to reaching a supervised or higher level of independence in UE dressing, rather than independence across multiple meaningful daily activities. It may be that UE training better facilitates independence in other activities.

Second, BADL training in stroke rehabilitation consists largely of teaching compensatory techniques for completing activities, such as 1-handed dressing techniques and prescribing adapted equipment to make 1-handed dressing activities easier (eg, providing a button hook). These techniques train a patient not to use his/her affected UE. Thus, increasing motor skills may indeed be unrelated to improvements in UE dressing because the patient is attempting to complete UE dressing tasks without using the affected UE. In addition, compensatory training in BADLs and IADLs may actually contradict the UE control training by encouraging learned nonuse of the affected UE.

A third reason for the lack of impact of UE control training on UE dressing ability is that, although occupational therapists spent a large percentage of their time on UE motor rehabilitation, in actual minutes this only averaged 10 to 12 minutes of direct UE motor control practice per session (although motor practice may have occurred during activities targeting other skills as well). This paucity of time devoted to motor practice contradicts an accepted principle of movement therapy: that intensity of practice is important.[30] Such a modest amount of time spent in training a motor skill is unlikely to facilitate enough motor recovery to affect dressing ability. Intensive therapy is an accepted principle of movement therapy.

In contrast, those patients who were unsuccessful at achieving a supervision level of independence in FIM UE dressing at discharge spent larger amounts of time in several lower-level activities than patients who were successful. These activities included wheelchair management, sitting balance, grooming, and feeding. Because these are more basic, it is likely that the amount of time spent in these activities reflects patient abilities. However, these data suggest that, at least for UE dressing, spending more time in these basic activities is not facilitating increased independence in this population. Obviously, this type of analysis will need to be repeated with outcomes in other patient-relevant activities and with other groups of patients with stroke to determine whether or not increased time on basic activities fails to promote improvements in function. Nonetheless, these data argue that it is important to understand the limits of our therapies in reaching certain functional outcomes.

Several limitations of this study warrant caution during interpretation of the results. The data about time in therapy activities and the percentage of patients who received each activity were gathered by therapists' reports. The therapy staff of each participating facility was highly engaged in the project. However, self-reports are open to several biases, such as social desirability. Although therapists were trained and given explicit definitions of activity categories, validation of how therapists classified the activities that they were providing was performed at the site level and may have been inconsistent among sites. Also, not all activity categories were mutually exclusive, either in definition or in clinical practice, which might have made it difficult for therapists to document which activity they were providing. For example, some mobility tasks could have fit in either bed mobility or functional mobility based on the definition, and a therapist could have been working on UE motor control simultaneously with dressing or grooming; however, there was no way to categorize more than 1 activity per 5-minute period. Another limitation is that we had only FIM scores available rather than impairment-level information for categorizing patient groups and outcomes. Occupational therapists most likely base treatment decisions on both client disability and impairments. Because patients can be heterogeneous in impairments and be in the same functional level, it is likely that different therapy treatments would be used with these patients. Also, we had no information about functional abilities in activities other than BADLs. Although independence in BADLs is important, it is far from a sufficient condition for full community participation and a satisfying quality of life. Rehabilitation should improve patients' quality of life.

Nonetheless, the aim of this study was to explore functional changes that take place within inpatient rehabilitation, and this study has numerous strengths in this area. It included a large number of geographically diverse patients in the United States, increasing the generalizability of these findings. The study used a detailed taxonomy of activities that was created by a team of both study personnel and practicing occupational therapists in the participating facilities, which resulted in data collection that was meaningful to practicing clinicians.

CONCLUSIONS

In this study, we examined types of activities that occupational therapists provided to patients during inpatient stroke rehabilitation. We discovered that occupational therapists provided a mixture of task training and restorative activities and that they tailored their therapy programs based on patient disability but did not seem to tailor therapy based on amount of OT. In patients who were admitted requiring at least maximum assistance in UE dressing, more time spent in higher-level activities (eg, community integration, functional mobility) was associated with a greater likelihood of reaching at least a supervised level of independence in FIM UE dressing.

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APPENDIX 1: OT INTERVENTION DOCUMENTATION FORM

Occupational Therapy Rehabilitation Activities

8646

Patient ID: Sample

Date of Therapy Session: / /

Therapist:

Time session begins: :

INTERVENTION CODES

Neuromuscular Interventions
01. Balance training
02. Postural awareness
03. Motor learning
04. PNF
05. NDT/Bobath
06. Brunstromm
07. Constrained induced movement therapy

Adaptive/Compensatory Interventions:
08. One-handed skills
09. Energy conservation
10. Environmental adaptation
11. Adaptive equipment

Musculoskeletal Interventions:
12. Strengthening
13. Mobilization, manual therapy
14. PROM/stretching
15. Edema control

Cardiopulmonary Interventions:
16. Breathing exercises
17. Aerobic/conditioning exercises

Cognitive/Perceptual/Sensory Interventions:
18. Cognitive training
19. Perceptual training
20. Visual training
21. Sensory training

Equipment Interventions:
22. Prescription/selection
23. Application
24. Fabrication
25. Ordering

Modality Interventions:
26. Electrical stimulation
27. Biofeedback
28. Hot/cold therapy

Education/Training Interventions:
29. Patient
30. Family/Caregiver
31. Staff

Assistive Devices:
32. Cane - Large base
33. Cane - Small base
34. Cane - Straight
35. Crutches - Axillary
36. Crutches - Forearm
37. Crutches - Small base forearm
38. Dowel
39. Grocery cart
40. Hemirail
41. Hi/low table
42. KAFO
43. Parallel bars
44. Platform (parallel bars or FWW)
45. Swiss ball
46. Tray table
47. Walker - FWW
48. Walker - Hemiwalker
49. Walker - Rising star
50. Walker - Standard
51. Wheelchair
Other:
52.
Area Involved:
53. Upper extremity
54. Trunk

Duration of Activity Enter in 5 minute increments.

Interventions Enter one intervention code per group of boxes.

- Pre-Functional Activity
- Bathing
- Dressing
- Grooming
- Toileting
- Feeding/eating
- Transfers
- Bed mobility
- Functional mobility
- Home management
- Community integration
- Leisure performance
- Upper extremity control
- Wheelchair management
- Sitting balance/trunk control
- Intervention not related to functional activity
- Intervention #2 not related to functional activity

Co-Treat:
No. of minutes: Disciplines:

Patient Assessment:
Formal Assessment (initial, re-evaluation, discharge): minutes
Home Evaluation: minutes
Work Site Evaluation: minutes

Occupational Therapy Time:
OT minutes | OT Assistant minutes | OT Aide/Tech minutes | OT Student minutes

Group Occupational Therapy Time:
OT Group/Dovetail minutes

Enter the number of each that participated in the Group OT:
Patients | Therapists | Assistants | Aides/Techs | Students

Abbreviations: FWW, front-wheel walker; KAFO, knee-ankle-foot orthosis; NDT, neurodevelopmental technique; PNF, proprioceptive neuromuscular fasciculation; PROM, passive range of motion.

APPENDIX 2: COMPONENT OF DRESSING, UPPER BODY

Dressing, Upper body: Includes dressing and undressing above the waist, as well as applying and removing a prosthesis or orthosis when applicable. Performs safely.

No helper	
7	Complete independence: Subject dresses and undresses including obtaining clothes from their customary places such as drawers and closets; manages bra, pullover garment, or front-opening garment; manages zippers, buttons, or snaps; applies and removes prosthesis or orthosis when applicable. Performs safely.
6	Modified Independence: Subject requires special adaptive closure such as Velcro, or as assistive device (including a prosthesis or orthosis) to dress, or takes more than a reasonable amount of time.
Helper	
5	Supervision or Setup: Subject requires supervision (eg, standing by, cuing, or coaxing) or setup (application of an upper body or limb orthosis/prosthesis or setting out clothes or dressing equipment).
4	Minimal Contact Assistance: Subject performs 75% or more of dressing tasks.
3	Moderate Assistance: Subject performs 50% to 74% of dressing tasks.
2	Maximal Assistance: Subject performs 25% to 49% of dressing tasks.
1	Total Assistance: Subject performs less than 25% of dressing tasks, or is not dressed.

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ORIGINAL ARTICLE

Characterizing Speech and Language Pathology Outcomes in Stroke Rehabilitation

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ABSTRACT. Hatfield B, Millet D, Coles J, Gassaway J, Conroy B, Smout RJ. Characterizing speech and language pathology outcomes in stroke rehabilitation. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S61-72.

Objectives: To describe a subset of speech-language pathology (SLP) patients in the Post-Stroke Rehabilitation Outcomes Project and to examine outcomes for patients with low admission FIM levels of auditory comprehension and verbal expression.

Design: Observational cohort study.

Setting: Five inpatient rehabilitation hospitals.

Participants: Patients (N=397) receiving poststroke SLP with admission FIM cognitive components at levels 1 through 5.

Interventions: Not applicable.

Main Outcome Measure: Increase in comprehension and expression FIM scores from admission to discharge.

Results: Cognitively and linguistically complex SLP activities (problem-solving and executive functioning skills) were associated with greater likelihood of success in low- to mid-level functioning communicators in the acute poststroke rehabilitation period.

Conclusions: The results challenge common clinical practice by suggesting that use of high-level cognitively and linguistically complex SLP activities early in a patient's stay may result in more efficient practice and better outcomes regardless of the patient's functional communication severity level on admission.

Key Words: Auditory perceptual disorders; Clinical practice patterns; Problem solving; Rehabilitation; Speech therapy; Stroke.

THE MIX OF SPEECH-LANGUAGE pathology (SLP) services in the poststroke population has been difficult to describe. Although there is a large body of literature that describes assessment, diagnoses, and activities involved in SLP services in the stroke population and the cognitive and communication sequelae that follow brain injury,[1-8] there is little to no research that adequately describes the interaction of these activities with the medical, physical, and emotional changes that occur with a stroke. SLP activities have been studied in isolation using broad categories based on speech and language diagnoses (ie, aphasia, dysarthria, dysphagia, cognitive-communication impairment). The interventions studied to date have been described subjectively or in structured research paradigms using a single selected treatment approach[9-12] and measuring change via performance on a specified task.

Many commonly used practices and treatment paradigms have little empiric evidence of their efficacy or effectiveness in the acute rehabilitation period. For example, use of group speech and language treatment has been studied in postacute populations[13,14] but not during the acute rehabilitation period. Although some universally validated practices exist in the area of diagnostics for the more tangible and technical aspects of SLP service provision (ie, modified barium swallow evaluations of dysphagia, video stroboscopic evaluations of vocal fold function), there is a paucity of data that describe the duration and timing of diagnostic activities and procedures as they relate to functional outcomes and success in SLP therapy.

Emphasis on achieving greater functional outcomes given diminishing lengths of stay (LOSs) during inpatient rehabilitation places clinicians in the daunting position of making constant adjustments to treatment plans based on each individual patient's needs. The complex nature of SLP services in stroke rehabilitation has limited the field's ability to conduct comprehensive studies that incorporate the interactions of comorbidities, leaving clinicians without firm guidance in how to prioritize activities while developing a treatment plan across a stroke patient's rehabilitation LOS. The policy of the American Speech-Language-Hearing Association is to provide evidenced-based practice, which is defined as "an approach in which current, high-quality research evidence is integrated with practitioner expertise and client preferences and values into the process of making clinical decisions."[15(p1)] However, there is no set protocol that describes which impairment to work on first or for what particular percentage of time, nor are there sufficient data to show that achieving a given performance level in a given area will enhance or detract from performance in other areas. It is left up to each individual clinician's instincts to adjust time spent in multiple activities using multiple interventions to try to achieve the most progress in the shortest possible period of time.

One of the primary reasons for the limitations in the current literature is the highly variable, complex nature of SLP activities and interventions. Rehabilitation of communication and swallowing is both an art and a science, and as yet, there has been no systematic way to compare practices or thoroughly capture what goes on during an inpatient rehabilitation stay and across settings. The objective of this article was to describe or characterize some basic aspects of SLP practice and the effects of specific SLP activities in achieving better outcomes for a subset of patients without a diagnosis of aphasia. We hypoth-

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esized that use of cognitively and linguistically complex SLP activities sooner in the rehabilitation stay is associated with better outcomes for patients who function as lower-level communicators at admission. This hypothesis stems from our clinical and anecdotal observations of patient performance and interactions in both one-on-one and group settings.

This article builds on the Post-Stroke Rehabilitation Outcomes Project (PSROP), a study of 1161 stroke rehabilitation patients discharged from 6 inpatient rehabilitation facilities (IRFs) in the United States. This article is limited to a subset of PSROP patients from 5 of these facilities. The motivation, purpose, scope, and key findings from the larger PSROP are provided in this supplement's introductory article.[16] A notable feature of the PSROP was the development of a taxonomy of rehabilitation activities and interventions associated with each clinical discipline, including SLP.[17] This taxonomy provided the methodologic breakthrough needed to characterize SLP activities and interventions discussed in the following sections.

METHODS

The methodology governing the full PSROP, provided in this supplement by Gassaway et al,[18] provides a detailed description of the larger study's participating facilities, patient selection criteria, data collection instruments including their validity and reliability, data collection instruments, and a detailed description of the project's final study group. The methodology is summarized in Maulden et al.[19] The institutional review boards at Boston University and at each participating IRF approved the study.

Patients in the SLP Subset

We examined a subset of the PSROP database that received at least 1 SLP session during rehabilitation as documented on project SLP intervention documentation forms. SLP sessions were documented for over 90% of patients in 5 U.S. sites. In the sixth PSROP site, at least 1 SLP session during rehabilitation was documented for only 14% of patients; thus, this site was not included in the SLP analyses presented here. Deleting this 1 site entirely and all those patients with no documented SLP sessions in the other sites left a patient population of 936 patients from 5 sites.

The next step was to identify the amount of SLP services that patients received. To investigate the demographics and functional outcomes of this patient population, the amount of SLP therapy received was divided into 3-hour blocks of time. For detailed analyses, we included all patients who received between 1 and eight 3-hour blocks (n=790) and excluded those patients who received less than 3 hours (n=86) or more that 24 hours (n=54) of SLP services. Because treatment approaches differ markedly between patients with and without a diagnosis of aphasia, we chose to exclude patients with a diagnosis of aphasia anywhere in the medical record and focused on the larger sample of 599 patients who did not have a diagnosis of aphasia. We recognize that some of these patients may have had some poststroke aphasia but that the diagnostic label was not documented in the medical record.

Because we hypothesized that patients without an aphasia diagnosis who present with severe communication deficits experience a greater improvement in expressive and receptive communication when exposed to cognitively complex SLP interventions (eg, problem-solving activities), we compared 2 subsamples: 1 of lower-level functionally communicating patients and 1 of mid-level functionally communicating patients, as determined by admission FIM cognitive component (comprehension, expression) scores. Appendix 1 provides a description of FIM levels for these components.

Patient sample 1 (low-level functional communicators). Sample 1a includes only patients with admission FIM comprehension levels 1 through 3. This provided a sample of 176 patients (without an aphasia diagnosis, with admission FIM comprehension levels 1–3, with 1 to eight 3-hour blocks of SLP) for initial analyses. To further define the low-level sample, we examined another subset of these patients with low admission FIM expression (levels 1–3). Sample 1b contains 141 patients without an aphasia diagnosis with both admission FIM comprehension and expression levels of 1 through 3.

Patient sample 2 (mid-level functional communicators). Sample 2a (n=221) includes only patients without an aphasia diagnosis with admission FIM comprehension levels of 4 and 5 who received 1 to eight 3-hour blocks of SLP. Sample 2b includes a subset of these patients (n=144) who also have admission FIM expression levels of 4 and 5.

Table 1 describes demographic information for the 2 patient samples combined (mid-level and low-level groups) by 3-hour blocks of SLP therapy. Patients with admission FIM comprehension levels of 6 and 7 were not considered in the analyses because specific SLP goals would not likely address comprehension with patients performing at this level.

Instrumentation

The SLP intervention documentation form (appendix 2) developed for the PSROP[18] included a finite taxonomy of information, such as the targeted activity area, interventions used by the clinician, and duration of each activity. Interventions were recorded to capture the specific approach the clinician took in addressing SLP goals within an activity area. For example, during a problem-solving activity, a clinician may have used verbal cueing to implement analysis and synthesis strategies with the patient to facilitate generation of alternative solutions. In contrast, during a task to target auditory comprehension, a clinician may have used verbal cueing to introduce analysis and synthesis strategies for drawing appropriate inferences from the task stimuli. Definitions for the activities and interventions contained on the SLP intervention documentation form were provided to practicing clinicians and are available on request. Additional information such as whether the session was individual or group, time spent in evaluation and planning, and potentially influential professional discussion of the patient among colleagues was also obtained; however, specific subtest scores from standardized tests commonly administered in SLP practice were not obtained. One SLP intervention documentation form was completed for each SLP session a patient received during his/her inpatient rehabilitation stay.

A lead SLP therapist from each IRF participated in a train-the-trainer teleconference to learn how to use and teach others to use the SLP intervention documentation form. After the teleconference, the lead SLPs trained colleagues in their respective IRFs.

Each site incorporated auditing of intervention documentation form use into routine site practices. Typically, the lead SLP therapist observed a patient session and completed a separate intervention documentation form based on what was observed. The therapist providing the session completed a form as per protocol. The lead therapist reviewed and discussed differences in completion with the practicing therapist.

Face validity was built into the intervention documentation forms because they were developed and used by IRF therapists as described. Predictive validity was assessed by showing significant effects of SLP interventions (and other therapy interventions) on outcomes.[20-22] For example, the amount of variation explained in discharge FIM score, controlling for

Table 1: Characteristics of Patients Without Aphasia Diagnosis and With Admission FIM Comprehension Levels 1 Through 5 (n=397)

Characteristics	1 Block (n=87)	2 Blocks (n=97)	3 Blocks (n=69)	4 Blocks (n=45)	5 Blocks (n=30)	6 Blocks (n=30)	7 Blocks (n=22)	8 Blocks (n=17)	Total (n=397)	P
Demographic characteristics										
Mean age (y)	66.1	67.9	69.5	70.3	63.0	67.7	64.6	67.3	67.5	.352*
Sex (% men)	43.7	52.6	58.0	48.9	56.7	40.0	50.0	76.5	51.4	.211†
Race (%)										.207†
White	71.3	67.0	60.9	48.9	66.7	70.0	72.7	76.5	65.7	
Black	17.2	17.5	20.3	15.6	20.0	20.0	9.1	5.9	17.1	
Other, including Hispanic	11.5	15.5	18.8	35.6	13.3	10.0	18.2	17.7	17.1	
Health and functional status characteristics										
Type of stroke (%)										.384†
Hemorrhagic	28.7	21.7	23.2	42.2	30.0	30.0	27.3	29.4	27.7	
Ischemic	71.3	78.4	76.8	57.8	70.0	70.0	72.7	70.6	72.3	
Side of stroke (%)										.522†
Right	50.6	48.5	37.7	68.9	43.3	56.7	54.6	58.8	50.4	
Left	34.5	37.1	39.1	24.4	33.3	36.7	27.3	35.3	34.5	
Bilateral	12.6	10.3	20.3	6.7	20.0	6.7	13.6	5.9	12.6	
Unknown	2.3	4.1	2.9	0.0	3.3	0.0	4.6	0.0	2.5	
Location of stroke (%)										.056†
Brainstem/cerebellum	18.4	12.4	17.4	17.8	36.7	10.0	9.1	17.7	16.9	
Subcortical	31.0	40.2	30.4	13.3	23.3	46.7	45.5	11.8	31.7	
Brainstem + subcortical	6.9	4.1	5.8	4.4	3.3	6.7	18.2	0.0	5.8	
Lobar (includes cortex)	37.9	37.1	40.6	53.3	33.3	33.3	22.7	58.8	39.3	
Unknown	5.8	6.2	5.8	11.1	3.3	3.3	4.6	11.8	6.3	
Mean admission total FIM score	64.4	61.7	56.4	52.7	50.2	51.5	49.3	45.7	57.4	<.001*
Mean admission motor FIM score	44.5	42.2	37.5	35.0	34.5	34.1	33.9	28.9	38.9	
Mean admission cognitive FIM score	19.9	19.5	19.0	17.6	15.6	17.7	15.4	17.4	18.5	.001*
Mean admission CSI	18.5	17.7	20.4	23.1	24.0	25.9	24.0	29.1	20.9	.002*
Prerehabilitation health care										
Mean time from stroke onset to rehabilitation (d)	12.1	14.1	14.6	16.4	17.9	8.3	13.0	10.6	13.7	.475*
Mean acute hospital LOS preceding rehabilitation (d)	12.2	15.3	18.9	20.6	23.6	26.8	30.6	34.7	19.0	<.001*

Abbreviation: CSI, Comprehensive Severity Index.
*Analysis of variance (ANOVA).
†Chi-square test.

patient characteristics (including admission FIM score, severity of illness, and demographic factors), was 40% for moderate strokes and 45% for severe strokes. When total time per day spent on physical therapy (PT), occupational therapy (OT), and SLP was added, there was no increase in variation explained for discharge FIM, consistent with previous findings by Bode et al.[23] However, when time per day spent in specific PT, OT, and SLP activities was added, the amount of variation explained increased to 52% for moderate strokes and 68% for severe strokes, adding 12% and 23% explanation of variation, respectively, in discharge FIM scores.

Functional performance for each study patient at admission to and discharge from inpatient rehabilitation was obtained via retrospective chart review using the study site's reporting of the FIM instrument.[24] We assumed that all clinicians providing FIM data within IRFs as part of standard practice were FIM credentialed; no additional documentation of FIM elements was performed for project purposes.

Data Analysis

Descriptive statistics were used to describe study variables. Patient, process, and outcome variables were compared using chi-square tests for categoric data and analysis of variance tests for continuous data. Correlation analyses were used to detect multicollinearity between predictor variables. Identified predictor variables and severity of illness were combined in logistic regression analyses to determine their concurrent effects on outcomes.

For logistic regression, a stepwise selection procedure with a significance level of .10 allowed independent variables to enter and leave the model. The importance of each variable in affecting an outcome was determined by the Wald chi-square statistic and odds ratio with 95% confidence interval. Discrimination c statistics (area under receiver operating characteristic curves) were used to evaluate how well each model distinguished, for example, patients who were successful in reaching the specified FIM level at discharge from patients who were not successful.

To examine the relation between SLP activities and outcomes, we used changes in FIM elements of auditory comprehension and verbal expression. These items were selected for analysis because they most directly describe the communication status of a patient and are measured independently of cognitive components that are frequently decreased in poststroke patients (ie, memory, problem solving, social interaction). Although SLP addresses these cognitive

Table 2: SLP Process Variables: Patients Without Aphasia Diagnosis and With Admission FIM Comprehension Level of 1 Through 5 (n=397)

Variables	1 Block (n=87)	2 Blocks (n=97)	3 Blocks (n=69)	4 Blocks (n=45)	5 Blocks (n=30)	6 Blocks (n=30)	7 Blocks (n=22)	8 Blocks (n=17)	All (n=397)
Mean LOS	12.2	15.3	18.9	20.6	23.6	26.8	30.6	34.7	19.0
Mean SLP intensity									
No. of days of therapy during rehab	5.0	8.1	11.0	13.5	16.3	18.6	22.0	24.8	11.4
No. of sessions during rehab	6.2	10.9	15.3	19.3	24.8	28.1	33.5	39.7	16.4
No. of minutes during rehab	214	376	556	724	914	1079	1304	1439	602
Mean SLP activities (% time)									
Swallowing + face/neck mobility	19.5	16.5	19.3	24.1	24.9	19.8	23.6	25.4	20.2
Speech/intelligibility	7.2	7.6	9.2	8.8	5.4	7.6	11.2	7.4	8.0
Voice	1.7	1.5	0.7	1.4	1.7	1.7	3.5	2.0	1.6
Verbal expression	12.5	11.8	8.9	8.4	9.7	5.8	10.4	7.8	10.2
Alternative/nonverbal expression	0.3	0.1	0.6	0.0	0.8	0.2	1.0	0.0	0.3
Written expression	2.6	3.4	2.9	1.4	3.0	1.7	1.1	3.5	2.6
Auditory comprehension	8.8	7.6	8.0	8.2	8.4	7.2	6.7	4.9	7.9
Reading comprehension	5.6	8.2	6.7	5.8	6.4	7.3	6.2	7.8	6.8
Problem solving/reasoning	16.7	19.1	17.8	17.7	18.8	24.9	15.6	19.5	18.4
Orientation	5.2	3.7	5.6	4.7	4.2	2.6	4.3	4.1	4.5
Attention	5.2	5.1	5.7	7.2	6.7	7.7	9.5	11.1	6.3
Memory	8.5	9.0	7.9	9.0	5.2	8.5	4.1	3.7	7.9
Pragmatics	0.1	0.9	1.0	0.4	1.1	0.6	0.5	0.1	0.6
Executive functioning skills	4.7	3.4	3.2	1.8	1.3	8.7	0.8	1.8	2.9
Prefunctional + activities not related to SLP skills	1.5	1.8	1.0	0.8	0.3	0.4	0.4	0.4	1.1

NOTE. Each patient in 1 block only, for example, patient with 20 total hours of SLP appears in block 6 only.

and linguistic areas through treatment, the variables of auditory comprehension and verbal expression best represent the functional ability of the patient to interact with the environment. To define success, we identified 2 markers for low-level patients and a different pair of markers for mid-level patients (one for improvement in comprehension, one for improvement in expression).

The first analysis defined success for low-level patients (admission FIM levels 1–3 for comprehension alone and then combined levels 1–3 for expression) as the discharge comprehension FIM score increasing by 2 or more levels; a second analysis defined success as the discharge expression FIM score increasing to level 4 (minimal assistance) or higher.

Mid-level patients (admission FIM levels 4–5 for comprehension alone and then combined with expression) were considered successful if the discharge FIM comprehension score increased to level 6 or higher and, in a second analysis, the discharge FIM expression score increased to level 6 or higher.

For purposes of interpreting and discussing the data, we classified SLP activities into categories of cognitively and linguistically simple, mid-level cognitively and linguistically complex, and high-level cognitively and linguistically complex based on a clinical consensus of the average complexity of activities and demands on a patient within a given activity. Cognitively and linguistically simple activities were those that addressed the most basic skill areas or were primarily motor based: swallowing, speech intelligibility, voice, alternative and nonverbal expression, orientation, and attention. The activity of "face/neck mobility" was combined with "swallowing" during analysis because of a low number of recordings for this category. Mid-level cognitively and linguistically complex activities were those that involved greater demands of the patient or were more abstract: verbal and written expression, auditory and reading comprehension, memory, and pragmatics. High-level cognitively and linguistically complex activities involved activities with the most multiple components: executive functioning skills, problem solving, and reasoning. Although patients do participate in complex tasks within activities that are considered simple (eg, divided attention tasks in community settings) and simple tasks within activities that are considered complex (eg, engaging problem solving by locating and using the nursing call bell to request assistance), we believed that this delineation best described the average usage of these activities by clinicians on a day-to-day basis.

RESULTS

This sample of 397 communicators with low- to mid-level functioning received a mean of 16.4 SLP therapy sessions over the course of their rehabilitation stays. These sessions were conducted over an average of 11.4 days and consumed an average of 602 minutes (table 2). Naturally, patients with 8 three-hour blocks of therapy received much more SLP therapy than patients with 1 to 3 blocks. Thus, for continued analyses, we included only time in each activity performed during the first block (3h) of SLP treatment time, regardless of the total number of SLP blocks of time a patient received over the whole rehabilitation stay (table 3). This ensured that patients were functioning at the identified communication level (as measured by admission FIM) at the time of participation in SLP activities. We did not measure incremental increases in FIM score during the rehabilitation stay, and therefore, it was important to reduce the confounding effect of function naturally improving over the course of

Table 3: SLP Process Variables: Patients Without Aphasia Diagnosis and With Admission FIM Comprehension Level of 1 Through 5 (n=397)

Variables*	1 Block (n=87)	2 Blocks (n=97) Time in 1st block	3 Blocks (n=69) Time in 1st block	4 Blocks (n=45) Time in 1st block	5 Blocks (n=30) Time in 1st block	6 Blocks (n=30) Time in 1st block	7 Blocks (n=22) Time in 1st block	8 Blocks (n=17) Time in 1st block	Mean % Time in All 1st Blocks
Swallowing + face/neck mobility	28.9	25.1	22.2	49.9	36.6	24.4	26.4	46.6	30.7
	15.1	22.4	29.4	23.8	39.4	44.8	30.5	35.3	25.3
Speech/intelligibility	2.6	3.4	7.5	3.4	3.7	4.4	3.9	6.1	4.1
	10.2	8.6	12.0	9.6	7.2	9.1	11.2	3.7	9.7
Voice	0.2	0.9	0.1	1.7	0.2	1.4	0.3	0.0	0.6
	2.3	1.8	0.6	2.3	2.9	0.2	0.0	4.0	1.7
Verbal expression	10.2	14.0	7.3	12.0	7.9	9.6	10.0	11.0	10.8
	13.2	6.0	8.1	4.4	7.1	1.6	10.5	0.1	7.7
Alternative/nonverbal expression	0.5	0.0	1.1	0.0	0.9	0.5	0.0	0.9	0.5
	0.3	0.2	0.0	0.0	0.0	0.0	1.9	0.0	0.2
Written expression	1.4	2.6	4.7	0.7	4.3	3.3	1.4	1.2	2.6
	2.7	2.0	1.9	1.4	0.8	2.5	0.0	3.3	2.0
Auditory comprehension	10.1	11.0	10.0	6.2	11.0	14.0	12.0	6.8	10.4
	8.1	5.7	6.7	9.2	6.0	0.3	8.7	3.7	6.6
Reading comprehension	3.7	8.4	9.0	4.4	7.0	2.9	4.2	2.8	5.9
	6.0	7.6	6.2	8.5	4.2	4.6	4.0	10.4	6.6
Problem solving/reasoning	12.8	7.2	10.0	3.8	12.6	15.0	3.0	4.7	9.3
	15.9	19.9	10.0	17.1	14.4	14.3	13.9	18.1	15.7
Orientation	9.3	7.9	9.6	6.7	5.3	5.2	8.4	6.9	7.7
	1.4	1.4	3.6	2.8	4.2	7.6	1.0	1.9	2.5
Attention	3.9	7.0	7.2	3.9	3.3	7.4	12.0	6.9	6.0
	6.1	2.5	3.1	7.4	6.5	1.4	3.3	19.0	4.7
Memory	11.3	6.7	4.2	5.9	1.5	4.5	4.1	5.2	6.1
	7.5	8.6	7.6	7.5	3.4	8.7	0.8	0.6	7.1
Pragmatics	0.1	0.2	0.3	0.6	0.6	0.2	1.0	0.0	0.3
	0.0	1.1	1.4	0.0	1.5	0.8	0.0	0.0	0.7
Executive functioning skills	2.9	1.7	0.8	0.0	1.9	0.0	0.0	0.0	1.3
	6.1	4.4	4.9	3.8	2.5	0.0	0.0	0.0	4.1
Prefunctional + activities not related to SLP skills	2.0	1.2	0.3	0.3	0.0	1.5	3.2	0.0	1.1
	1.2	4.2	2.7	2.4	0.0	0.0	5.2	0.0	2.4

NOTE. Each patient in 1 block only: for example, patient with 20 total hours of SLP appears in block 6 only. Percentage of time spent in the first 3-hour block only is displayed.
*SLP activities mean percentage of time. First line of each variable is for patients with admission FIM comprehension level 1–3 (n=176). Second line of each variable is for patients with admission FIM comprehension level 4–5 (n=221).

rehabilitation. Had we examined time in activities later in the stay, the outcomes at discharge could have been confounded with the natural recovery process or performance of other activities. In using the first block, we hypothesized that patients would not have had time to improve in their functioning, as they might have if we had included all blocks (2–8) in regression analyses.

For these communicators with low- to mid-level functioning, the total and cognitive FIM scores increased by means of 27.7 and 5.4, respectively, from admission to discharge. Changes in FIM scores from admission to discharge and discharge destination as related to number of SLP therapy blocks for this patient sample are presented in table 4.

Logistic Regression

We allowed many variables (eg, demographics, admission functioning level, medical severity of illness, stroke locations; see table 1) to enter stepwise selection procedures to identify variables associated with greater or less likelihood of patients achieving our defined success outcomes. Because admission FIM motor and cognitive scores aggregate functional information across different activities, 2 patients with very different disabilities may have an identical score composed of higher and lower levels from different areas. This means that use of motor and cognitive scores may not adequately control for patients' starting disability levels. To overcome this concern, we performed an additional set of regression models allowing individual motor and cognitive components of the FIM to enter instead of admission FIM motor and cognitive scores. In addition, we allowed number of minutes during the first therapy block for each SLP activity (eg, swallowing, orientation, problem solving) to enter the model. Another variable allowed to enter was the FIM discharge bladder level, because bladder function and level of continence can be considered a surrogate indicator for overall cognitive-communication functioning level. Patients with lower-level cognitive and communication function typically have lower awareness of the need to void and/or the ability to obtain necessary help for toileting to maintain continence. Bladder function seems to be an indicator of potential for recovery, a difference between those who succeed and those who

Table 4: PSROP SLP Outcome Variables: Patients Without Aphasia Diagnosis and With Admission FIM Comprehension of Levels 1 Through 5 (n=397)

Variables	1 Block (n=87)	2 Blocks (n=97)	3 Blocks (n=69)	4 Blocks (n=45)	5 Blocks (n=30)	6 Blocks (n=30)	7 Blocks (n=22)	8 Blocks (n=17)	Total (n=397)	P
FIM										
Mean discharge total FIM score	88.6	86.6	85.1	81.9	78.8	86.0	76.7	83.3	84.9	.192*
Mean discharge FIM bladder component score	5.3	5.1	4.9	4.8	4.9	5.2	4.4	4.5	5.0	.577*
Mean increase in total FIM score (discharge − admission)	24.3	25.5	28.5	29.0	28.3	34.1	27.5	38.6	27.7	.003*
Mean discharge motor FIM score	63.9	62.2	60.6	58.9	57.6	61.3	55.0	57.8	60.9	.346*
Mean increase in motor FIM score (discharge − admission)	19.6	20.6	23.0	24.0	23.1	27.0	21.1	30.1	22.3	.023*
Mean discharge cognitive FIM score	24.5	24.4	24.5	22.7	20.9	24.7	21.8	25.5	23.9	.035*
Mean increase in cognitive FIM score (discharge − admission)	4.6	4.9	5.5	5.1	5.3	7.0	6.4	8.1	5.4	.015*
Discharge destination (%)										.143†
Inpatient institutional discharge	18.4	17.5	21.7	26.7	40.0	16.7	31.8	11.8	21.7	
Community discharge including home	81.6	82.6	78.3	73.3	60.0	83.3	68.2	88.2	78.3	
Home	79.3	80.4	69.6	73.3	60.0	80.0	68.2	88.2	75.6	.203†
Admission FIM comprehension level 1–3 (n=176)										
Increase in comprehensive component score of ≥2 levels from levels 1–3 (% patients)	40.0	45.0	56.0	47.4	30.0	75.0	63.6	80.0	50.0	.054†
Increase in expression component score from level 1–3 to ≥level 4 (% patients)	54.3	67.5	64.0	57.9	65.0	87.5	36.4	70.0	63.1	.223†
Admission FIM comprehension level 4–5 (n=221)										
Increase in comprehensive component score from level 4–5 to ≥6 (% patients)	59.6	59.7	52.3	38.5	30.0	42.9	54.6	71.4	53.4	.350†
Increase in expression component score from level 4–5 to ≥level 6 (% patients)	53.9	63.2	54.6	50.0	40.0	50.0	18.2	57.1	53.4	.280†

*ANOVA.
†Chi-square test.

do not. The level of continence has been established as a compelling factor in determining discharge disposition.[25]

Sample 1

Logistic regression analyses predicting increase in FIM comprehension and expression scores for communicators with low-level function are presented in table 5.

In sample 1a (176 patients without aphasia diagnosis, with admission FIM comprehension levels 1–3), 50% (88 patients) achieved success. Even after controlling for multiple patient characteristics, creating otherwise matched groups, several mid-level and complex SLP activities were associated with greater likelihood of success in these low-level patients, including more time spent in problem-solving and executive functioning activities in the first 3-hour block. Several SLP activities were associated with less likelihood of success: more time spent in orientation, verbal expression, and written expression activities. Low-level bladder functioning by the time of discharge was also associated with less likelihood of success (c=.812). Bladder function appears to covary with improvement in communication-cognitive function.

When we removed admission FIM motor and cognitive scores and allowed the motor and cognitive components of FIM to enter individually, the model remained the same, including for SLP activities associated with greater or less likelihood of success.

For the subset of 141 patients with FIM admission levels 1 through 3 for both comprehension and expression (sample 1b) and with success defined as reaching FIM expression level 4 or higher by discharge (77 [55%] patients successful), similar results were found: more time spent doing a cognitively and linguistically complex SLP activity (problem solving) during the first 3-hour block was associated with greater likelihood of success, as was high bladder functioning at discharge. Mid-level and simple SLP activities (eg, reading comprehension, memory) were associated with less likelihood of success (c=.849).

When we removed admission FIM motor and cognitive scores and allowed the motor and cognitive components of FIM to enter individually, similar SLP activities were associated with greater or less likelihood of success (c=.886).

Sample 2

Logistic regression analyses predicting increase in FIM comprehension and expression for communicators with mid-level functioning are presented in table 6.

Table 5: Logistic Regression Analyses Predicting Increase in FIM Comprehension and Expression for Communicators With Low-Level Functioning Without a Diagnosis of Aphasia (Sample 1)

Sample 1a: 176 Patients, Admission FIM Comprehension Levels 1–3					Sample 1b: 141 Patients, Admission FIM Comprehension Levels 1–3 and Admission FIM Expression Levels 1–3				
Variables	Parameter Estimate	Wald χ^2 Test	*P*	Odds Ratio	Variables	Parameter Estimate	Wald χ^2 Test	*P*	Odds Ratio
Outcome = increase of ≥2 FIM comprehension levels from admission to discharge (88 patients/50% success) (c=.805)					Outcome = increase in FIM expression from levels 1–3 at admission to ≥ level 4 at discharge (77 patients/54.6% success) (c=.849)				
Successful variables					Successful variables				
SLP activity problem solving	0.03	6.01	.014	NA	SLP activity problem solving	0.07	13.75	<.001	NA
SLP activity executive functioning	0.08	6.62	.010	NA	LOS	0.10	13.63	<.001	NA
LOS	0.11	20.87	<.001	NA	Hemorrhagic stroke	1.29	6.72	.010	1.4–9.6
Unsuccessful variables					Higher admission FIM cognitive score	0.20	10.94	.001	NA
SLP activity verbal expression	−0.02	4.68	.030	NA	FIM discharge bladder level 1-3	2.11	18.21	<.001	3.1–21.7
SLP activity written expression	−0.05	4.76	.029	NA	Unsuccessful variables				
FIM discharge bladder level 1-3	−1.83	17.89	<.001	.07–.36	SLP activity reading comprehension	−0.05	5.03	.025	NA
Female	−1.02	7.11	.008	.15–.71					
Brain location brainstem/cerebral	−1.86	10.89	.001	.05–.44					
If we remove admission motor and cognitive scores and allow motor and cognitive components to enter, 88 patients/50% success (c=.805)					If remove admission motor and cognitive scores and allow motor and cognitive components to enter (77 patients/55% success) (c=.886)				
Same as above					Successful variables				
					SLP activity problem solving	0.06	6.45	.011	NA
					SLP activity executive functioning	0.13	4.55	.033	NA
					LOS	0.11	14.42	<.001	NA
					Higher admission FIM component expression	1.41	14.29	<.001	NA
					Unsuccessful variables				
					SLP activity reading compression	−0.05	6.14	.013	NA
					FIM discharge bladder level 1–3	−2.90	21.36	<.001	.02–.19
					FIM discharge bladder level 4–5	−1.29	4.45	.035	.08–.91
					Female	−1.17	5.46	.020	.12–.83

NOTE. Variables allowed to enter the model include admission FIM motor and cognitive scores; admission CSI score; increase in severity; net medical improvement; side of stroke: left, right, bilateral; hemorrhagic stroke; location in brain: lobar, subcortical, brainstem/cerebral, subcortical; diabetes diagnosis; female; race: black, white, other; hospital inpatient stay >20 days; admission FIM bladder level: 1–3, 4–5, 6–7; SLP activities in first 3-hour block: swallowing, speech/intelligibility, voice, verbal expression, alternative nonverbal expression, writing expression, auditory comprehension, reading comprehension, problem solving/reasoning, orientation, attention, memory, pragmatics, executive functioning, nonfunctional. Reference variables were brain side unknown, brain location unknown, and race unknown.
Abbreviation: NA, not applicable.

When we repeated regression analyses with sample 2a (221 patients without an aphasia diagnosis and with admission FIM comprehension scores of 4 and 5), again we found that more time spent performing mid-level and simple SLP activities (auditory comprehension) in the first 3-hour block of SLP time was associated with less likelihood of success (discharge FIM comprehension level ≥6) and more time spent in the complex activity of problem solving was associated with greater likelihood of success (c=.788). Removing admission FIM motor and cognitive scores and allowing the motor and cognitive components of FIM to enter individually produced similar results, including the SLP activity of problem solving associated with greater likelihood of success (c=.844).

When controlling for admission expression level in addition to comprehension (sample 2b), more time spent in problem-solving activities again was associated with greater likelihood of success, whereas more time spent in verbal expression was associated with less likelihood of success (c=.808). Similar results were found when we removed admission FIM motor and cognitive scores and allowed the motor and cognitive components of FIM to enter individually (c=.872).

DISCUSSION

For most patients without an aphasia diagnosis, PSROP data indicate that use of activities involving problem solving is associated with greater likelihood of improved outcomes in verbal expression and auditory comprehension. These results indicate that perhaps problem-solving activities, which by their nature involve critical thinking, mental flexibility, integration of multiple components of information, and mental manipulation, generally lead to better auditory processing and inferencing skills, as measured via auditory comprehension FIM data, as well as to increased capacity for discourse, as measured via verbal expression FIM data. Taking a top-down therapeutic approach naturally may recruit a greater number of cognitive and linguistic skills (ie, error detection, revision/repair, self-

Table 6: Logistic Regression Analyses Predicting Increase in Comprehension and Expression for Mid-Level Functional Communicators: Patients Without Aphasia Diagnosis (Sample 2)

Sample 2a: 221 Patients With Admission FIM Comprehension Levels 4–5					Sample 2b: 144 Patients With Admission FIM Comprehension Levels 4–5 and Admission FIM Expression Levels 4–5				
Variables	Parameter Estimate	Wald χ^2 Test	*P*	Odds Ratio	Variables	Parameter Estimate	Wald χ^2 Test	*P*	Odds Ratio
Outcome = increase in FIM comprehension level from 4–5 at admission to ≥6 at discharge (114 patients/52% success) (*c*=.788)					Outcome = increase in FIM expression from levels 4–5 at admission to ≥ level 6 at discharge (75 patients/52% success) (*c*=.824)				
Successful variables					Successful variables				
SLP activity problem solving	0.01	2.80	.094	NA	SLP activity problem solving	0.03	7.90	.005	NA
Higher admission cognitive score	0.16	13.70	<.001	NA	Race white	0.99	4.31	.038	1.1–6.9
LOS	0.06	7.80	.005	NA	Higher admission FIM cognitive score	0.22	10.54	.001	NA
Unsuccessful variables					FIM discharge bladder level 6–7	1.45	7.68	.006	1.5–11.9
SLP activity auditory comprehension	−0.05	12.28	<.001	NA	Unsuccessful variables				
Higher admission CSI score	−0.03	3.83	.050	NA	SLP activity verbal expression	−0.02	5.28	.022	NA
FIM discharge bladder level 1–3	−1.17	5.36	.021	.12–.84	Hemorrhagic stroke	−1.36	6.13	.013	.09–.75
					Higher admission CSI score	−0.07	7.95	.005	NA
					Higher admission FIM motor score	−0.08	12.35	<.001	NA
If remove admission motor and cognitive scores and allow motor and cognitive components to enter (116 patients/53% success) (*c*=.844)					If remove admission motor and cognitive scores and allow motor and cognitive components to enter (76 patients/53% success) (*c*=.867)				
Successful variables					Successful variables				
SLP activity problem solving	0.02	5.12	.024	NA	SLP activity problem solving	0.03	4.89	.027	NA
Higher admission FIM component memory	0.46	12.51	<.001	NA	FIM discharge bladder level 6–7	1.57	8.91	.003	1.7–13.4
Higher admission FIM component comprehension	1.75	24.06	<.001	NA	Higher admission FIM component expression	2.39	22.33	<.001	NA
LOS	0.06	7.53	.006	NA	LOS	0.08	6.50	.011	NA
Unsuccessful variables					Unsuccessful variables				
SLP activity auditory comprehension	−0.04	6.45	.011	NA	Higher admission FIM component toilet transfer	−0.56	5.38	.020	NA
Higher admission CSI score	−0.03	5.36	.021	NA	Race other	−1.45	3.91	.048	.05–.99
					Higher admission CSI score	0.08	8.87	.003	NA
					Hemorrhagic stroke	−1.72	7.82	.005	.05–.60

NOTE. Variables allowed to enter the model include admission FIM motor and cognitive scores; admission CSI score; increase in severity; net medical improvement; side of stroke: left, right, bilateral; hemorrhagic stroke; location in brain: lobar, subcortical, brainstem/cerebral, subcortical; diabetes diagnosis; female; race: black, white, other; hospital inpatient stay >20 days; admission FIM bladder level: 1–3, 4–5, 6–7; SLP activities in first 3-hour block: swallowing, speech/intelligibility, voice, verbal expression, alternative nonverbal expression, writing expression, auditory comprehension, reading comprehension, problem solving/reasoning, orientation, attention, memory, pragmatics, executive functioning, nonfunctional. Reference variables were brain side unknown, brain location unknown, and race unknown.

regulation) that trickle down into expanded and strengthened components of functional language (ie, inferencing, expanded semantic and syntactic constructs). These areas are often decreased in poststroke patients without a diagnosis of aphasia[8] and have at their roots a breakdown in the integration of information versus true comprehension and formulation deficits, as in those with aphasia. Clinicians did report working on individual activities of auditory comprehension and verbal expression in isolation with patients without a diagnosis of aphasia; however, the data suggest that addressing these target areas in an integrated manner results in more improvement than working on each deficit area in isolation.

The strengths of this study are many, because the breadth of the data collected and large number of subjects allowed for the formulation of homogenous groups for comparison. It also provided a comprehensive look at what patients actually experience at the hands of SLPs in a natural setting. The weaknesses of the study, however, are related to the strengths, in that multiple objective and subjective choices about how to carve out homogeneous groups were required. Additionally, despite the best efforts of clinical leaders at each site to promote accuracy and consistency in use of the intervention documentation forms, the reality of busy clinicians completing additional paperwork per treatment session may have resulted in quick decision making about the true nature of activities and interventions performed. The documentation form did not allow for recording the context in which an activity was performed, which also may have an impact on the functional outcome for a patient. For example, if a clinician addresses problem solving by using real-life materials such as bank checks or newspaper coupons, the patient's performance, involvement, and benefit from the task may be different than the same goals targeted in a hypothetical, fabricated context. However, despite these limitations, significant variation in outcomes

was found associated with differences in time spent per day in specific SLP activities.

The clinical implications of these results are potentially great, because they indicate that offering mid- to high-level cognitively and linguistically complex activities earlier in a patient's episode of care is more likely to result in favorable outcomes. Generally, clinical consensus in SLP practice is to select an activity and intervention strategy at just a notch in complexity above the current functional performance of the patient, gradually increasing complexity as the patient progresses to maintain a relatively high patient success rate.[26] Initiating complex tasks within the first 3 hours of treatment seems counterintuitive at first. However, results of this study indicate that doing so may increase significantly the patient's likelihood of advancing their independence in functional communication skills. Additionally, current practice techniques tend to match an activity with a category of impairment—that is, if a patient has decreased auditory comprehension, a clinician will select activities and use interventions directly targeting auditory comprehension. Results of this study indicate that more time spent in tasks of analysis and synthesis of information improves both verbal expression and auditory comprehension, although neither was specifically addressed via those tasks. Results also indicate that collaboration between SLP and OT early on in a patient's rehabilitative stay potentially could improve other FIM areas such as continence. For example, accessing and using a call bell system to convey the need for toileting activates a patient's simple cognitive-linguistic skills (ie, initiation of functional problem solving and of conveying a basic need) as a means to enhance both auditory comprehension and verbal or nonverbal communication. Addressing these skills provides the SLP with a starting point to tap into each patient's cognitive and linguistic skills using meaningful and purposeful activities that naturally increase functional communication outcomes.

It appears that challenging a patient early in the rehabilitation stay and addressing multicomponent integration and mental manipulation tasks potentially has far-reaching effects. Asking patients who present with low linguistic ability to perform more complex cognitive and linguistic tasks may require more clinician cueing and assistance but appears to be associated with more efficient generalization of skills, as indicated by functional performance at discharge.

Future research implications of this study's results include using these findings to guide controlled trials of trends that rose above the noise of this large data set. Results could be correlated with standardized test measures of speech and language performance, such as the auditory comprehension and verbal expression subtests of the Western Aphasia Battery.[27] Further analyses of PSROP data could ask different questions about current practice principles. Examining specific interventions used within each complex SLP activity, as well as specific activities and interventions used with patients with a diagnosis of aphasia, time spent in initial and interim evaluation, clinical practice variation across specific clinicians and treatment sites, and use of treatment groups will further our understanding of these current results.

CONCLUSIONS

For every practicing clinician who works with poststroke patients in inpatient rehabilitation there is a unique set of guiding principles, intervention techniques, and management styles learned from a body of literature, overt teaching and mentoring, experience, and pure instinct. For every stroke survivor who participates in an inpatient rehabilitation program there is a unique set of functional goals, comorbidities, learning style, and attitude toward recovery.

Historically, SLP treatment plans have been driven by individual clinician rationale; however, given the rather surprising evidence drawn from these data regarding the complexity of activities SLPs offer stroke rehabilitation patients early in their treatment, there is a clear need for further investigation of factors that drive clinician decision making, as well as patient variables that may impact the functional success or failure of achievement in a targeted skill area. The primary objective of this article was to test the hypothesis that use of cognitively and linguistically complex SLP activities early in a patient's stay may result in better outcomes, regardless of the patient's functional communication severity level on admission, but clearly further examination is both necessary and welcome. Future data analyses will provide a more detailed description of specific interventions and activities used in acute stroke rehabilitation with an eye toward determining best practices that will guide the type of activities, timing, frequency, duration, and interventions that make up the provision of SLP services with poststroke patients during inpatient rehabilitation.

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APPENDIX 1: FIM SCORING LEVELS FOR COGNITIVE COMPONENTS: COMPREHENSION AND EXPRESSION

Comprehension

Includes understanding of either auditory or visual communication (eg, writing, sign language, gestures). Records the more usual modality (auditory, visual, or both).

7 Complete independence: subject understands directions and conversation that are complex or abstract; understands either spoken or written language.
6 Modified independence: in most situations, subject understands complex or abstract directions and conversation readily or with only mild difficulty. No prompting is needed. May require a hearing aid or other assistive device or extra time to understand the information.
5 Standby prompting: subject understands directions and conversation about basic daily needs more than 90% of the time. Requires prompting (slowed speak, use of repetition, stressing of particular words or phrases, pauses, visual or gestural cues) less than 10% of the time.
4 Minimal prompting: subject understands directions and conversation about basic daily needs 75% to 90% of the time.
3 Moderate prompting: subject understands directions and conversation about basic daily needs 50% to 74% of the time.
2 Maximal prompting: subject understands directions and conversation about basic daily needs 25% to 49% of the time. Understands only simple, commonly used expressions or gestures. Requires prompting more than half the time.
1 Total assistance: subject understands directions and conversation about basic daily needs less than 25% of the time, does not understand simple, commonly used spoken expressions or gestures, or does not respond appropriately or consistently despite prompting.

NOTE: Comprehension of complex or abstract information includes but is not limited to understanding current events appearing in television programs or newspaper articles or abstract information on subjects such as religion, humor, math, or finances used in daily living. This may also include information given during group conversation. Information about daily needs refers to conversation, directions, questions, or statements related to a subject's need for nutrition, fluids, elimination, hygiene, or sleep.

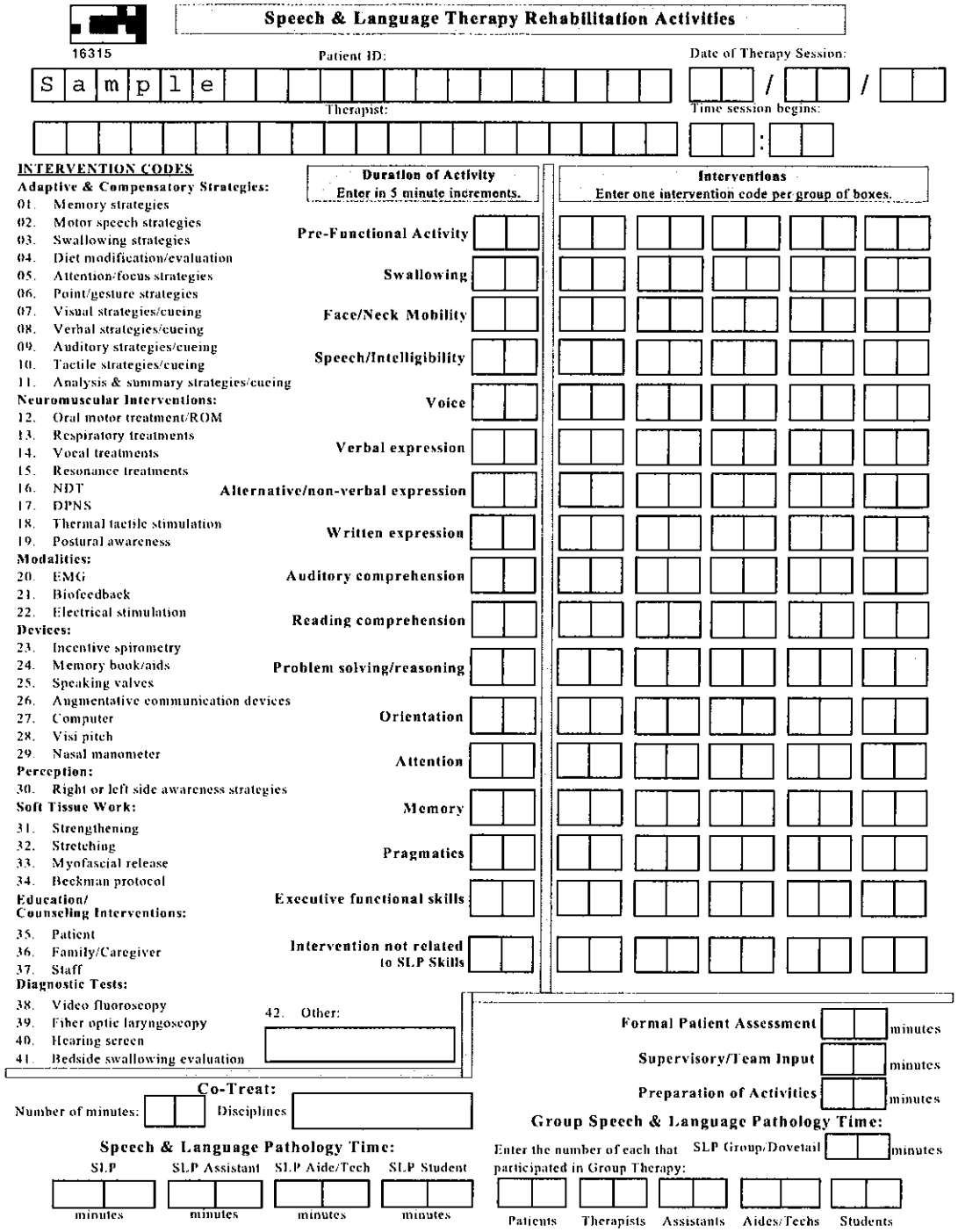
Expression

Includes clear vocal or nonvocal expression of language. This item includes either intelligible speech or clear expression of language using writing or communication device. The item records the more prevalent modality (vocal, nonvocal, or both).

7 Complete independence: subject expresses complex or abstract ideas clearly and fluently, not necessarily in English.
6 Modified independent: in most situations, subject expresses complex or abstract ideas relatively clearly or with only mild difficulty. No prompting is needed. May require an augmentative communication device or system.
5 Standby prompting: subject expresses basic daily needs and ideas more than 90% of the time. Requires prompting (eg, frequent repetition) less than 10% of the time to be understood.
4 Minimal prompting: subject expresses basic daily needs and ideas 75% to 90% of the time.
3 Moderate prompting: subject expresses basic daily needs and ideas 50% to 74% of the time.
2 Maximal prompting: subject expresses basic daily needs and ideas 25% to 49% of the time. Uses only single words or gestures. Needs prompting more than half the time.
1 Total assistance: subject expresses basic daily needs and ideas less than 25% of the time or does not express basic needs appropriately or consistently despite prompting.

NOTE: Examples of complex or abstract ideas include but are not limited to discussing current events, religion, or relationships with others. Expression of basic needs and ideas refers to a subject's ability to communicate about necessary daily activities such as nutrition, fluids, elimination, hygiene, and sleep.

APPENDIX 2: SLP INTERVENTION DOCUMENTATION FORM*



Abbreviations: DPNS, direct pharyngeal nerve stimulation; EMG, electromyography; NDT, neurodevelopmental technique; ROM, range of motion.
*Definition of terms available on request.

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ORIGINAL ARTICLE

An Exploration of Central Nervous System Medication Use and Outcomes in Stroke Rehabilitation

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ABSTRACT. Conroy B, Zorowitz R, Horn SD, Ryser DK, Teraoka J, Smout RJ. An exploration of central nervous system medication use and outcomes in stroke rehabilitation. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S73-81.

Objective: To study associations between neurobehavioral impairments, use of neurotropic medications, and outcomes for inpatient stroke rehabilitation, controlling for a variety of confounding variables.

Design: Observational cohort study of poststroke rehabilitation.

Setting: Six inpatient rehabilitation hospitals in the United States.

Participants: Patients with moderate or severe strokes (N=919).

Interventions: Not applicable.

Main Outcome Measures: Discharge disposition, FIM score change, and rehabilitation length of stay (LOS).

Results: Neurobehavioral impairments and use of many medications, including first-generation selective serotonin reuptake inhibitors, older traditional antipsychotic medications, and anti-Parkinsonian neurostimulants, have a statistical association with poorer outcomes, whereas use of the atypical antipsychotic medications has a positive association with improvement in motor FIM scores. Counterintuitively, use of opioid analgesics is associated with a larger motor FIM score change but not an increase in LOS or reduced percentage of discharge to community. There was significant variation in use of neurotropic medications among the 6 study sites during inpatient stroke rehabilitation.

Conclusions: There are many opportunities to enhance a stroke survivor's ability to benefit from acute inpatient stroke rehabilitation through improved understanding of associations of neurotropic medications with outcomes for different patient groups.

Key Words: Antipsychotic agents; Clinical practice variations; Rehabilitation; Stroke; Treatment outcome.

ANNUAL MEDICARE EXPENDITURES for hospital-based rehabilitation in the United States reached $5.9 billion in 2004.[1,2] Stroke, a leading cause of adult onset disability, is the second leading cause for admission to inpatient rehabilitation and is associated with high costs and intensive utilization of rehabilitation resources.[3-5] Neurologic and behavioral impairments, such as delirium, dementia, agitation, anxiety, apathy, psychomotor slowing, impulsivity, and depression, are common in stroke survivors and can have a negative association with participation in therapy, length of stay (LOS), discharge disposition, resultant functional outcome, and ultimate quality of life.[6-15]

Stroke-related depression literature[6-15] states that depression is probably the most common neurologic and behavioral impairment disorder after stroke, that it occurs in 30% to 50% of stroke patients,[8] and that depressive symptoms and pharmacologic treatments extend well beyond the first few weeks after stroke.[7-15] Importantly, there are studies that have found that major depression may not become diagnosable until several months after stroke onset.[16] In contrast, during the immediate poststroke period—when patients are most likely to undergo intensive rehabilitation therapy—other mood and behavior disturbances are more prevalent than a major depressive disorder, but few studies exist on this subject.[6] Examples of neurologic and behavioral impairments that can occur soon after the onset of a stroke and can interfere with rehabilitation care include apathy, agitation, anxiety, insomnia, psychosis, disinhibition, adjustment disorder with depressed mood, delusions, delirium, abulia, pathologic affect, psychomotor slowing, neurogenic and somatic pain, mania, catastrophic reactions, and poststroke fatigue. Several pharmacologic classes of medications (eg, benzodiazepines, antipsychotics, sedatives and hypnotics, anticonvulsants, stimulants, antidepressants) often are used empirically, alone or in combinations, to treat these symptoms. Some of these medications, such as benzodiazepines, the anticonvulsants phenytoin and phenobarbital, and older dopamine receptor antagonists have been associated with poorer upper-extremity motor function and less independence in activities of daily living 84 days poststroke.[17]

According to current literature, the potential benefit of choosing 1 neurotropic medication over another in poststroke mood and behavior disturbances other than depression is particularly unclear, especially in the early poststroke interval (0–4wk after stroke). Do newer neurotropic medications (usually more costly) offer substantial benefits compared with the older, less expensive, and more commonly used medications? Limited access to newer agents because of formulary cost control, as well as a limited number of studies in stroke patients, has impeded the adoption of these medications in clinical practice, thus hindering clinical knowledge of potential benefits.[18] Judicious study of selected neurotropic medications,

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such as olanzapine or quetiapine in poststroke patients with agitation or delirium as opposed to buspirone, benzodiazepines, or haloperidol, has potential to affect outcomes.

Many reasons exist for the paucity of information on effects of neurotropic medications in stroke rehabilitation. There is a concern whether randomized control methods for this type of study are ethically and logistically appropriate in this population. Cognitive and emotional aberrations often affect recruitment into clinical trials because of lack of understanding or altered mental status; randomized controlled trials often exclude these types of impairments. Henon et al[19] found evidence of preexisting dementia in 16% of a series of admissions to their stroke unit. Interactions between the mechanism and anatomic location of the brain lesion in relation to the timing of drug administration, which are not understood completely, may influence a drug's apparent impact on functional recovery.[20]

Analysis of the Post-Stroke Rehabilitation Outcomes Project (PSROP) database uncovered significant variation in the use of medications among 6 U.S. inpatient rehabilitation facilities (IRFs) that cannot be explained by patient differences.[21] This was especially evident in those agents specifically used for their effects on the central nervous system. Physician preferences seemed to be primary determinants of medication choice. Drug formulary restrictions, experience using a particular medication, and other factors may influence physicians' prescriptions.

This study attempts to identify neurotropic medication treatments associated with better outcomes with regard to mood, behavioral, and/or cognitive impairments in stroke rehabilitation. We hypothesize that use of medications that modulate the noradrenergic, dopaminergic, cholinergic, and serotinergic neuroendocrine systems is associated with better outcomes after stroke rehabilitation. A secondary hypothesis is that newer neuroleptic medications are associated with better outcomes compared with older neuroleptic agents. Newer antipsychotic agents purportedly have mechanisms of action that are more effective than older antipsychotics and have a lesser side-effect profile; thus they are better tolerated in patients with stroke and the elderly at risk of iatrogenic disturbances.

METHODS

The methodology governing the full PSROP is discussed in the article by Gassaway et al,[21] which provides a detailed description of the larger study's participating facilities, patient selection criteria, data collection instruments including their validity and reliability, and a detailed description of the project's final study group. The methodology is summarized in Maulden et al.[22] The institutional review boards at Boston University and at each participating IRF approved the study.

Patient Variables

PSROP patient variables[21] included age, sex, race, payer, type and location of stroke, admission FIM instrument score, case-mix group (CMG), time from stroke symptom onset to rehabilitation admission, and severity of illness. The Comprehensive Severity Index (CSI), the study's principal severity-of-illness adjuster, is a disease-specific severity assessment system that provides a consistent method for defining levels of severity using over 2200 individual physical findings and laboratory results.[23-27] The CSI was measured separately for admission to rehabilitation (first 24h), discharge from rehabilitation (discharge day), and maximum (the full rehabilitation stay, including admission and discharge periods).

Process Variables (Including Medications)

Details about each neurotropic medication received by study patients were obtained, including drug name, dose, frequency (including as required [PRN] or regular dosing), route of administration, start date and time, and stop date and time. For medications to be included in the PSROP database, the medication needed to be initialized as given on the medication administration record in the patient's chart. PRN medications that were ordered but not given were not included.

We grouped neurotropic medications into categories by consensus of prescribing members of the PSROP clinical team based on similarity of drug content and effects on patients. Drug categories (structured roughly around medication groupings found in ePocrates[28]) used in these analyses are listed in table 1 along with the medications they contain.

Outcome Variables

PSROP outcome variables include rehabilitation LOS, discharge FIM and CSI scores, functional gain as measured by increased FIM score from admission to discharge, increase in severity of illness as measured by increase in CSI from admission to maximum, and discharge disposition.[21]

Patient Subsample With Neurobehavioral Impairment

In the 1161-subject U.S. PSROP sample, we identified patients with indications of neurobehavioral impairment, defined as mood and behavioral disturbances, cognitive impairment, both, or symptoms of neither but presence of certain neurotropic medications indicative of previously treated symptoms. Patients were included in the neurobehavioral impairment group if they met 1 of 3 selection criteria, each of which is analyzed as an independent variable:

1. One or more neurobehavioral impairment diagnoses (eg, major depression, *International Classification of Diseases, 9th Revision, Clinical Modification*,[29] codes 296.2–.3) were documented in their chart.
2. A charted description of a neurobehavioral impairment that included mood or behavioral disturbances and cognitive impairments was documented in their chart. Descriptors for mood or behavioral disturbances included combative, agitated, restless, aggressive, anxious, depressed, emotionally labile, having hallucinations, flat affect, and impulsive. Descriptors for cognitive impairment included decreased safety awareness, impaired or poor judgment or concentration, impaired memory, confused, disoriented, and lethargic.
3. Use of specific neurotropic medications (antidepressants, benzodiazepines, anxiolytics, antipsychotics) without charted descriptions of neurobehavioral impairments or presence of neurobehavioral impairment diagnoses codes. We hypothesized that these patients received medication to continue symptom control.

CMGs were combined into moderate (CMGs 104–107) and severe (CMGs 108–114) stroke patient groups, which were large enough to detect small effects. There were too few patients with mild stroke to be analyzed at this time (CMGs 101–103; n=108).

To include the full inpatient rehabilitation course in these analyses, patients discharged to other acute facilities were excluded (n=134). This left 474 patients in the moderate stroke group and 445 patients in the severe stroke group to allow us to evaluate effectiveness of various medication approaches, including polypharmaceutical combination therapies found to be of benefit in a recent study of long-term-care patients.[18]

Table 1: Descriptions of Medication Categories

Therapeutic Class (No. of Times Therapeutic Class Medication Administered)	Medications Included in Therapeutic Class and No. of Times Each Medication Administered	
Atypical antipsychotics (n=208)	Clozapine	2
	Olanzapine	112
	Quetiapine	51
	Risperidone	43
Traditional antipsychotics (n=47)	Haloperidol	34
	Chlorpromazine	9
	Fluphenazine HCl	1
	Thioridazine	3
Tricyclic antidepressants (n=69)	Amitriptyline	40
	Clomipramine	1
	Desipramine	1
	Doxepin	5
	Imipramine	4
	Nortriptyline	18
Old SSRIs (n=357)	Fluoxetine	59
	Paroxetine	112
	Sertraline	186
New SSRIs (n=167)	Citalopram	126
	Escitalopram	41
Other antidepressants (n=520)	Trazodone	457
	Bupropion	25
	Mirtazepine	23
	Nefazodone	1
	Venlafaxine	14
Analgesic, muscle relaxant (n=197)	Baclofen	76
	Carisoprodol	3
	Cyclobenzaprine	14
	Dantrolene	54
	Metaxalone	4
	Methocarbamol	3
	Tizanidine	43
Anti-Parkinson's medications (n=174)	Bromocriptine	10
	Pergolide	1
	Pramipexole	3
	Carbidopa/levodopa	63
	Amantadine	97
Anxiolytics (n=39)	Buspirone	39
Hypnotics (n=337)	Zalepion	1
	Zolpidem	336
Other neurologics (n=78)	Modafinil	78
Neurostimulants (n=235)	Dexedrine	3
	Methylphenidate	232
Opioid analgesics (n=536)	Codeine	71
	Fentanyl	20
	Hydrocodone	182
	Hydromorphone	8
	Meperidine	3
	Methadone	4
	Morphine	56
	Oxycodone	177
	Propoxyphene	15
New antinausea/vomiting medications (n=61)	Dolasetron	2
	Ondansetron	59
Old antinausea/vomiting medications (n=204)	Dronabinol	2
	Droperidol	7
	Metoclopramide	110
	Prochlorperazine	38
	Promethazine	42
	Trimethobenzamide	5

Table 1 (Cont'd): Descriptions of Medication Categories

Therapeutic Class (No. of Times Therapeutic Class Medication Administered)	Medications Included in Therapeutic Class and No. of Times Each Medication Administered	
Sedating antihistamines (n=123)	Chlorpheniramine	1
	Cyproheptadine	2
	Diphenhydramine	87
	Hydroxyzine	33
Benzodiazepines (n=261)	Alprazolam	16
	Clonazepam	27
	Diazepam	13
	Chlordiazepoxide	1
	Lorazepam	137
	Midazolam	2
	Oxazepam	2
	Temazepam	58
	Clorazepate	1
	Triazolam	4
Old anticonvulsants (n=55)	Carbamazepine	26
	Divalproex	23
	Valproate sodium	5
	Valproic acid	1
New anticonvulsants (n=215)	Lamotrigine	1
	Levetiracetam	18
	Gabapentin	193
	Topiramate	2
	Oxcarbazepine	1
Anticonvulsants: detrimental to cognition (n=287)	Fosphenytoin	2
	Phenobarbital	9
	Phenytoin	271
	Primidone	5

Abbreviation: SSRIs, selective serotonin reuptake inhibitors.

Statistical Methods

We performed a systematic analysis to examine associations of various neurobehavioral impairments and neurotropic medication categories with stroke rehabilitation outcomes using descriptive statistics, 2-way associations, analysis of variance, correlation analyses, and ordinary least squares or logistic regression analyses. We controlled for important covariates, such as admission functional status (FIM instrument), severity of illness (CSI), and comorbidities, by using detailed patient data contained in the PSROP database.[21]

RESULTS

Descriptive Statistics

Table 1 lists specific medications that were included in each neurotropic medication group. Each group contains multiple medications used in PSROP facilities; however, there is often a predominate medication. For example, gabapentin accounts for 90% of all new anticonvulsants.

Patients with moderate stroke (CMGs 104–107) had different demographic and other characteristics than patients in CMGs 108 to 114 (severe stroke). There were 345 (72.8%) patients in the moderate stroke group who had a documented neurobehavioral impairment or received neurotropic medications, compared with 381 (85.6%) patients in the severe stroke group ($P<.001$) (table 2).

There were several other significant differences between the moderate and severe stroke CMG patient groups. Patients with severe stroke were sicker as measured by admission and maximum CSI scores (higher), more functionally disabled as measured by FIM scores (lower), had higher percentage of hemorrhagic (vs ischemic) strokes, and had longer LOSs. A smaller percentage of patients with severe stroke were discharged to home (73.3% vs 95.2%).

Neurotropic medication use served as a surrogate for indication of neurobehavioral impairment for 23% of patients in both groups.

Associations of Neurologic and Behavioral Impairments With Outcomes by CMGs

Associations between neurobehavioral impairment and outcomes by severity of stroke are shown in table 3. For patients with moderate strokes, having both of the defined components of neurobehavioral impairment (mood and behavior disturbances, cognitive impairment) was associated with the longest LOS (17.3d). Patients with no documentation (diagnosis, chart descriptions, or neurotropic medication use) of neurobehavioral impairment had the shortest LOS (12.9d, $P<.001$) and the highest rate of discharge to home (99.2%).

For patients with severe strokes, having the mood and behavior disturbances component or both components (mood and behavioral disturbances, cognitive impairment) was associated with a longer mean LOS (≥26d), whereas patients in the severe group with no indication of neurobehavioral impairment had the shortest LOS for their group (22.1d, $P=.030$). Also, patients with severe stroke with both components of neurobehavioral impairment had significantly less improvement in motor FIM score and were more likely to be discharged to a skilled nursing facility (SNF). Patients with severe stroke with neurotropic medications only had the largest increase in motor FIM score and the lowest percentage of discharge to an SNF. In addition, the presence of cognitive impairment was associated

Table 2: Descriptive Statistics for Patients in Moderate (CMGs 104–107) and Severe (CMGs 108–114) Stroke Groups

Variables	CMGs 104–107 (n=474)	CMGs 108–114 (n=445)	P
Female (%)	50.0	47.6	.509*
Mean age ± SD	65.4±14.8	67.8±14.1	.013†
Age groups (%)			.224*
19–40y	5.5	3.8	
41–60y	26.4	23.2	
61–80y	52.1	53.0	
>80y	16.0	20.0	
Race (%)			.060*
White	56.5	56.4	
Black	28.1	24.5	
Other	14.4	18.4	
Missing	1.1	0.7	
Side of stroke (%)			.727*
Right	45.4	43.4	
Left	42.8	43.4	
Bilateral	9.1	11.0	
Unknown	2.7	2.3	
Type of stroke (%)			.063*
Hemorrhagic	21.3	26.7	
Ischemic	78.7	73.3	
Neurobehavioral impairments (%)			<.001*
Mood/behavior disturbances	36.5	36.2	
Cognitive impairment	4.4	7.6	
Both	8.9	18.4	
Neurotropic medications	23.0	23.4	
None	27.2	14.4	
Discharge disposition (%)			<.001*
Home/community	95.2	73.3	
SNF	4.8	28.7	
Mean admission CSI continuous score ± SD	16.0±10.2	26.7±14.7	<.001†
Mean maximum CSI continuous score ± SD	23.3±14.2	40.1±21.9	<.001†
Mean discharge CSI continuous score ± SD	6.0±6.8	14.1±12.9	<.001†
Mean increase (maximum − admission) in CSI score ± SD	7.3±8.0	13.4±12.2	<.001†
Mean admission motor FIM score ± SD	47.9±5.6	27.0±7.1	<.001†
Mean discharge motor FIM score ± SD	70.2±9.4	51.5±16.3	<.001†
Mean Increase motor FIM score ± SD	22.4±8.8	24.5±13.9	.006†
Mean admission cognitive FIM score ± SD	24.2±7.2	16.9±7.7	<.001†
Mean discharge cognitive FIM score ± SD	27.9±6.0	22.2±7.6	<.001†
Mean increase cognitive FIM score ± SD	3.7±3.7	5.3±4.6	<.001†
Mean LOS ± SD	15.2±7.2	24.9±10.5	<.001†

Abbreviations: SNF, skilled nursing facility; SD, standard deviation.
*Chi-square test.
†*t* test.

most strongly with a higher percentage of patients discharged to an SNF in both the moderate and severe stroke groups.

Table 4 presents significant associations between neurotropic medication groups and 2 outcomes: rehabilitation LOS and increases in motor FIM score. Patients with moderate and severe stroke who received medications within specific neurotropic medication groups are compared with all patients in each group, controlling for patient characteristics (listed below table 4). Patients with moderate stroke (n=20) who were given atypical antipsychotic medications are compared with a control group of patients with moderate stroke who did not receive any atypical antipsychotic medicine. Patients given atypical antipsychotics statistically had the same LOS (15.7d) but a significantly improved motor FIM score with a change of 27.8 points as compared with the overall mean LOS and change in motor FIM score for the moderate stroke control group (15.2d and 22.4 points, respectively).

For patients with moderate stroke, neurotropic medication groups associated with significantly longer rehabilitation LOSs were the traditional antipsychotics, modafinil, hypnotics, anxiolytics, anti-Parkinson's medications, and newer selective serotonin reuptake inhibitors (SSRIs). Newer SSRIs, atypical antipsychotics, and opioid analgesics were associated with significantly greater increase in motor FIM score. Use of older antinausea medications, tricyclic antidepressants, anti-Parkinson's medications, muscle relaxants, neurostimulants, and older SSRIs was associated with significantly less increase in motor FIM score.

For patients with severe strokes, use of muscle relaxants, anti-Parkinson's medications, anxiolytics, hypnotics, new antinausea medications, sedating antihistamines, or traditional antipsychotics was associated with significantly longer rehabilitation LOSs. For these same severe patients, use of older SSRIs, anti-Parkinson's medications, and modafinil was associated with significantly less improvement in motor FIM score,

Table 3: Bivariate Associations of Neurobehavioral Impairment With Outcomes by CMG Group

Variables	Mood/Behavior Disturbances (n=334)	Cognitive Impairment (n=55)	Both Mood/Behavior Disturbances and Cognitive Impairment (n=124)	Neurotropic Medications (No Mood/Behavioral/Cognitive Impairment Signs Recorded) (n=213)	None (n=193)	P
LOS (d)						
CMGs 104–107 (n)	173	21	42	109	129	
Mean LOS ± SD	16.2±6.5	15.2±6.8	17.3±9.1	15.4±7.9	12.9±6.3	<.001*
CMGS 108–114 (n)	161	34	82	104	64	
Mean LOS ± SD	26.4±9.9	22.6±9.4	26.0±12.3	24.2±10.7	22.1±9.4	.030*
Mean increase motor FIM score ± SD						
CMGs 104–107	22.5±8.5	22.1±10.2	20.5±7.1	21.5±10.1	23.5±8.1	.271*
CMGs 108–114	25.4±13.2	21.8±22.4	20.6±14.3	26.4±11.5	25.4±12.6	.034*
Discharge disposition (%)						
CMGs 104–107						<.001†
Home	97.1	81.0	85.7	93.6	99.2	
SNF	2.9	19.0	14.3	6.4	0.8	
CMGs 108–114						.003†
Home	72.7	61.8	61.0	83.7	79.7	
SNF	27.3	38.2	39.0	16.3	20.3	

NOTE. CMGs 104–107: moderate stroke; CMGs 108–114: severe stroke.
*Analysis of variance.
†Chi-square test.

but use of hypnotics was associated with significantly more improvement in motor FIM.

Tables 5 and 6 show, for each PSROP facility, the percentage of patients who received medications in the neurotropic medication groups found to be associated with better or poorer outcomes (see table 4). Use of neurotropic medications varied significantly among the facilities for patients with moderate (see table 5) and severe strokes (see table 6), with the latter group having the greatest variation. Site variation is noticeable in the increase or decrease of neurotropic medication use as the severity of the stroke increases. For example, at site 4, use of new SSRIs is infrequent for all patients and use of old SSRIs increases from 27% for patients with moderate stroke (see table 5) to 52% for patients with severe stroke (see table 6). In contrast, at site 5

Table 4: Associations of Types of Medications and Outcomes by CMG Groups

Variables	CMG 104–107 (n=474)			CMG 108–114 (n=445)		
Therapeutic Medication Class	n	Mean LOS (mean, 15.2)*	Mean Increase Motor FIM Score (mean, 22.4)*	n	Mean LOS (mean, 24.9)†	Mean Increase Motor FIM Score (mean, 24.5)†
Atypical antipsychotics	20	15.7 (+0.5)	27.8‡ (+5.4)	53	26.9 (+2.0)	25.6 (+1.1)
Traditional antipsychotics	7	18.4§ (+3.2)	22.1 (−0.3)	10	37.4‡ (+12.5)	24.5 (same)
Tricyclic antidepressants	15	18.6 (+3.4)	20.2§ (−2.2)	21	25.1 (+0.2)	25.8 (+1.3)
Old SSRIs	90	16.5 (+1.3)	21.3§ (−1.1)	104	25.8 (+0.9)	21.4‖ (−3.1)
New SSRIs	31	19.5§ (+4.3)	24.2§ (+1.8)	59	29.3 (+4.4)	25.9 (+1.4)
Analgesic; muscle relaxant	23	18.0 (+2.8)	19.3‡ (−3.1)	43	30.2‡ (+5.3)	23.0 (−1.5)
Anti-Parkinson's medications	41	18.0§ (+2.8)	18.1‖ (−4.3)	68	28.4‡ (+3.5)	22.8‡ (−1.7)
Anxiolytics	4	23.8§ (+8.6)	19.8 (−2.6)	13	36.2‡ (+11.3)	27.6 (+3.1)
Hypnotics	87	17.2§ (+2.0)	21.5 (−0.9)	96	28.1‡ (+3.2)	27.5‡ (+3.0)
Modafinil	2	32.0 (+16.8)	29.0 (+6.6)	32	27.7 (+2.8)	21.1§ (−3.4)
Neurostimulants	16	19.9 (+4.7)	18.0‖ (−4.4)	57	28.4 (+3.5)	22.1 (−2.4)
Opioid analgesics	86	15.8 (+0.6)	24.7‡ (+2.3)	115	27.1 (+2.2)	25.2 (+0.7)
New antinausea/vomiting medications	15	15.9 (+0.7)	21.3 (−1.1)	34	29.2§ (+4.3)	24.7 (+0.2)
Old antinausea/vomiting medications	41	17.3 (+2.1)	20.0‡ (−2.4)	76	27.3 (+2.4)	24.7 (+0.2)
Sedating antihistamines	43	16.8 (+1.6)	23.5 (+1.1)	31	29.8§ (+4.9)	26.6 (+2.1)

NOTE. Values are means for patients with the specified medication and, in parentheses, the difference between cell mean value and overall mean for all patients in the CMG. Patient characteristics controlled in regression analyses include sex, age, race, side of stroke, type of stroke, mental status, pre–prospective payment system, discharge disposition, maximum CSI continuous score, admission motor FIM score, and admission cognitive FIM score.
*Mean of entire group (n=474).
†Mean of entire group (n=445).
‡Significance of variable between .001 and .01 in multiple regression analyses of outcome, controlling for patient characteristics.
§Significance of variable between .01 and .05 in multiple regression analyses of outcome, controlling for patient characteristics.
‖Significance of variable less than .001 in multiple regression analyses of outcome, controlling for patient characteristics.

Table 5: Percentage of Patients With Moderate Stroke (CMG 104–107) Using Specified Medication Categories by Site

Therapeutic Medication Class	Sites						P*
	1	2	3	4	5	6	
Atypical antipsychotics	4.1	4.4	4.3	1.8	11.9	2.2	.049
Tricyclic antidepressants	4.1	2.2	4.3	5.4	1.7	1.1	.529
Old SSRIs	13.7	14.3	12.8	26.8	17.0	22.8	.098
New SSRIs	2.7	11.0	2.1	4.5	18.6	2.2	<.001
Analgesic; muscle relaxant	0.0	2.2	4.3	11.6	5.1	3.3	.005
Anti-Parkinson's medications	1.4	23.1	0.0	0.0	5.1	17.4	<.001
Hypnotics	37.0	34.1	10.6	8.0	25.4	0.0	<.001
Neurostimulants	2.7	3.3	4.3	0.0	10.2	3.3	.029
Opioid analgesics	4.1	23.1	36.2	14.3	25.4	15.2	<.001
New antinausea/vomiting medications	1.4	2.2	6.4	1.8	11.9	0.0	<.001
Old antinausea/vomiting medications	2.7	18.7	12.8	7.1	11.9	1.1	<.001

*Chi-square test.

the overall use of old SSRIs is less frequent and the use of newer SSRIs increases as stroke severity increases.

DISCUSSION

Patients with severe strokes (CMGs 108–114) were older; were sicker at admission to, discharge from, and during their rehabilitation stays (CSI scores); were less likely to be discharged to home; and had longer LOSs than patients with moderate strokes. However, both patients with severe and moderate strokes had about the same increase in motor FIM and cognitive FIM scores from admission to discharge from rehabilitation. Within the moderate and severe stroke CMG groupings patients with no neurobehavioral impairments (no mood or behavior disturbances, no cognitive impairment, and no use of neurotropic medications) had the shortest LOSs and larger increases in motor FIM. When severity of illness (CSI) and its related components were not allowed to enter models by not including them in the variable selection list, the R^2 and c statistics changed little. Because none or very few of the other predictors changed, the models were stable.

We found several neurotropic medications associated with better outcomes and others that were associated with poorer outcomes. These varied by patient characteristics and severity of stroke. Generally, the newer medications (eg, newer SSRIs, atypical antipsychotics) were associated with better outcomes. Newer SSRIs were associated with greater improvement in FIM scores but also were associated with longer LOSs, making it difficult to draw definite conclusions about overall benefit. Older antinausea medications were associated with less FIM improvement for patients with moderate stroke and had no effect on LOS, suggesting a rationale for using the newer antinausea agents in this patient population, because the older antinausea medications may reduce FIM efficiency. Finally, atypical antipsychotics generally were associated with more increase in motor FIM score (primarily in the moderate stroke group), corresponding to our initial hypothesis that the more favorable side-effect profile of the atypical antipsychotic medication group in patients with stroke should translate into better outcomes.

Most facilities used newer medications sparingly. However, site 5 used newer SSRIs, newer antinausea medications, neurostimulants, and atypical antipsychotic medications more frequently, for patients with both moderate and severe stroke. After controlling for many patient characteristics (see table 2), we found that the association of neurobehavioral impairments with better or poorer outcomes in bivariate analyses remained significant in multiple regression analyses for LOS and increase in motor FIM score. That is, after using more thorough efforts to control for multiple patient characteristics in multiple

Table 6: Percentage of Patients With Severe Stroke (CMG 108–114) Using Specified Medication Categories by Site

Therapeutic Medication Class	Sites						P*
	1	2	3	4	5	6	
Atypical antipsychotics	4.9	7.6	3.4	2.2	40.7	4.9	<.001
Traditional antipsychotics	3.7	4.6	1.7	0.0	1.1	2.4	.533
Tricyclic antidepressants	3.7	1.5	10.1	4.4	1.1	4.9	.035
Old SSRIs	24.4	15.2	18.5	52.2	12.1	41.5	<.001
New SSRIs	2.4	13.6	5.9	8.7	37.4	7.3	<.001
Other antidepressants	8.5	21.2	58.8	15.2	49.5	48.8	<.001
Analgesic; muscle relaxant	3.7	9.1	10.1	15.2	12.1	9.8	.339
Anti-Parkinson's medications	1.2	48.5	10.1	0.0	3.3	48.8	<.001
Anxiolytics	4.9	0.0	4.2	4.4	1.1	2.4	.391
Hypnotics	32.9	60.6	4.2	6.5	23.1	0.0	<.001
Modafinil	0.0	0.0	0.0	0.0	35.2	0.0	<.001
Neurostimulants	11.0	7.6	5.9	2.2	30.8	17.1	<.001
Opioid analgesics	4.9	24.2	42.0	23.9	36.3	2.4	<.001
New antinausea/vomiting medications	2.4	0.0	4.2	2.2	27.5	2.4	<.001
Old antinausea/vomiting medications	15.9	30.3	18.5	6.5	14.3	12.2	.021

*Chi-square test.

sequences and combinations, outcomes consistently were better for patients with atypical antipsychotic medications than without.

There are a number of questions that can be raised about these initial observations. Many of these medications may have been used off-label in ways that their medication category description would not suggest. For instance, low-dose chlorpromazine is often used as a cure for intractable hiccups, and haloperidol is rarely used in poststroke rehabilitation except in the case of an elderly person who may be demented and experiencing sundowning. Use of anti-Parkinson's neurostimulants has entirely different implications in the absence of Parkinson's disease (of all the study patients who were given anti-Parkinson's medications, only 3.9% had a documented diagnosis of Parkinson's disease). Future analyses will attempt to understand discrepant uses of medications of interest.

However, there is evidence in the literature that these medications might be beneficial and justifies investigation of their effectiveness. During the early 1980s, studies were conducted on animals investigating the use of adrenergic agents on brain recovery after injury.[30-32] Later, Gualtieri[33] and Goldstein[17] published articles advocating that other adrenergic agents, as well as their precursors, could facilitate recovery. Studies on the use of dopamine agonists (so-called "anti-Parkinson agents") for brain injury in humans began in the 1990s, showing that these agents also could be used to help initiation and attention in these patients.[34-40] Dopamine agonists have since been used commonly in the treatment of brain injury. The use of dopamine agonists in patients with stroke so far has been limited to anecdotal or pilot studies; however, these articles are suggestive of their ability to facilitate cognitive capacity and recovery.

A meta-analysis of 7 generally high-level studies involving a total of 172 patients suggested that amphetamine treatment reduced death and dependence and relatively improved motor and language function.[41] However, there were too few patients to draw any definite conclusions about effects of amphetamine treatment on recovery from stroke. A randomized, double-blind, placebo-controlled trial of 40 subjects using intravenous amantadine or placebo for 5 days showed statistically significant improvements in cadence, length of heel-to-toe movements in the single support phase, and variability in double support phase and double support time.[42] A prospective, randomized, placebo-controlled, double-blind study of physical therapy combined with 3 weeks of daily levodopa or placebo and then 3 weeks of physical therapy alone showed increased motor function at both endpoints. Finally, 21 stroke survivors randomized to methylphenidate or placebo for 3 weeks scored lower on one depression scale and higher on a functional scale.[43]

Atypical antipsychotics, particularly olanzapine, have been reported to enhance cognitive function, providing a possible basis for the positive association of these medications with better outcomes during stroke rehabilitation.[44-46] These positive reports need to be balanced with recent controversy about the off-label use of atypical antipsychotics in the management of elderly patients with dementia. A U.S. Food and Drug Administration Public Health Advisory[47] in April 2005 warned that a review of 17 controlled trials involving the use of atypical antipsychotics in elderly demented patients showed a 1.6- to 1.7-fold increase in mortality, mostly because of heart-related events and pneumonia. Like the present study, this report only indicates an association of increased mortality with these medications in a population with some similarity to our stroke population, not a cause-and-effect relation. Caution and further investigation are needed to confirm these findings.

Finally, we have not yet examined the specific ramifications of medication dosing, duration, or timing or medications being given simultaneously or in sequence. Nonetheless, these findings add to the body of quantified knowledge of how a stroke survivor is treated during poststroke inpatient rehabilitation and strengthen previously established observations that limiting access to newer medications may lead to higher overall costs through longer LOSs without concomitant improvements in motor FIM score change or rate of discharge to community.[18,48]

CONCLUSIONS

We found significant differences in the ways stroke rehabilitation physicians approach common neurocognitive impairments after stroke and in the choice of medications to lessen their negative impacts. This exploration of neurotropic medication utilization practice patterns and outcomes can be used to guide the design of future studies to enhance the efficient use of inpatient stroke rehabilitation resources and improve patient outcomes. Although they do not confirm a cause-and-effect relation, our results indicate that certain medications or classes of medications are associated with positive and negative effects on stroke rehabilitation outcomes and should be studied further.

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ORIGINAL ARTICLE

Nutrition Support (Tube Feeding) as a Rehabilitation Intervention

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ABSTRACT. James R, Gines D, Menlove A, Horn SD, Gassaway J, Smout RJ. Nutrition support (tube feeding) as a rehabilitation intervention. Arch Phys Med Rehabil 2005; 86(12 Suppl 2):S82-92.

Objective: To describe site variation in use of enteral feeding and its association with stroke rehabilitation outcomes, controlling for a variety of confounding variables.

Design: Prospective observational cohort study.

Setting: Six inpatient rehabilitation facilities in the United States.

Participants: Patients (N=919) from the Post-Stroke Rehabilitation Outcomes Project database with moderate or severe stroke who were discharged to home, community, or skilled nursing facility.

Interventions: Not applicable.

Main Outcome Measures: Change in total, motor, and cognitive FIM instrument scores and change in severity of illness.

Results: Monitoring of nutritional status and the frequency of tube-feeding interventions for patients with moderate and severe stroke varied significantly among sites. Patients with tube feeding had higher severity of illness and lower functioning on admission compared with patients who did not receive tube feeding. However, when we controlled for severity of illness, admission FIM score, and other important covariates, we found that patients with severe strokes who were tube fed for more than 25% of their stay had greater increases in total, motor, and cognitive FIM scores and greater improvement in severity of illness by discharge.

Conclusions: Nutrition support (tube feeding) is an effective therapy in rehabilitation service for patients with severe strokes and is associated with greater motor and cognitive improvements, even in patients with the most severe strokes.

Key Words: Cerebrovascular accident; Nutrition; Outcome assessment (health care); Rehabilitation; Severity of illness index; Tube feeding.

MANY PATIENTS IN STROKE rehabilitation have some degree of malnutrition, either from prior poor food intake or from demands imposed by the stroke and hospitalization.[1] It is a known problem in stroke patients, with a prevalence of 16% on admission that increases to 22% to 35% at about 2 weeks and up to 50% at 2 to 3 weeks.[2-4] Malnourished people may lack the energy, stamina, strength, and mental focus to participate fully in therapies.[5,6] The effect of poor nutritional status on patients with stroke has been associated with poorer outcomes, such as reduced functional improvement, longer lengths of stay (LOSs), increased rates of complications, and mortality.[7,8] However, nutrition is often overlooked or not included as an important poststroke rehabilitation intervention, although it has been shown to be a foundation for effective therapy.[9]

Most inpatient rehabilitation facility patients have varying degrees of limitations related to eating, such as dysphagia, cognitive impairment, limited mobility, and movement.[10] Often enteral (using the gastrointestinal system) feeding by mouth, although the most natural and desirable feeding method, is complicated by a lack of ability to self-feed, chewing or swallowing difficulties, poor appetite, and prior food preferences and patterns that are closely linked to malnutrition, weight loss, and decreased strength.[11] Altered-consistency diets (eg, puree, blended, or ground foods) and thickened liquids frequently are given to patients with chewing and swallowing difficulties but may be unappealing and contribute to poor intake. Nutritional support (enteral feeding by tube) provides adequate nutrition and is not affected by reduced appetite, swallowing problems, limited self-feeding, or disease conditions in which the gastrointestinal system is compromised. Tube feeding enhances continued physical recovery, supports earlier initiation of rehabilitation efforts, and may reduce aspiration related to dysphagia.[12]

Optimal timing to initiate tube feeding and for which patients have not been defined clearly.[13,14] The decision begins, in most cases, during the acute hospital stay before rehabilitation. A physician assesses each patient and if the patient is deemed to be at risk for aspiration based on diagnosis or poor tolerance of oral intake, a referral is made for a bedside (or clinical) swallow study. Approximately 60% of aspiration occurs without sensation or outward signs and symptoms and often would not be diagnosed from clinical examination.[15] Therefore, if a patient appears at risk for silent aspiration or if further assessment is warranted, an instrumental swallow study is performed. If a safe diet can be established during a clinical or instrumental examination, with or without the use of compensatory strategies and diet modification, all attempts are made to maintain an oral route. If a patient is unable to meet nutritional needs and/or adequately protect his/her airway with oral intake, then temporary alternative measures for nutrition and hydration, such as tube feeding, are recommended.[16-18] However, the time between trying to feed by oral intake and identifying that oral intake is unable to meet a patient's nutri-

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tional needs delays the initiation of tube feeding, which may result in nutritional decline.[19]

Clinicians must weigh the perceived risk of silent aspiration caused by dysphagia against the known association of nasogastric tubes that are used commonly for short-term tube feedings with increased rates of aspiration pneumonia.[20-24] To truly weigh the risks, it is important to understand the full benefit of tube feeding on functional status and cognition.

The aim of this article was to describe the variation of nutritional support interventions, specifically tube feeding, used during poststroke inpatient rehabilitation and to determine the association of tube-feeding interventions with functional and clinical outcomes and patients' abilities to participate in physical therapy (PT), occupational therapy (OT), and speech and language pathology (SLP) sessions. Our hypothesis was that patients who present with similar functional and cognitive levels (measured by FIM instrument scores) and severity of illness (measured by the Comprehensive Severity Index [CSI]) and who receive tube feeding during acute rehabilitation to provide additional nutritional support have better participation in therapies and, hence, better outcomes. This may be the first study to explore site variation in tube-feeding practice in inpatient rehabilitation and associate tube-feeding interventions with rehabilitation outcomes.[24]

METHODS

Patient Sample

We used the Post-Stroke Rehabilitation Outcomes Project (PSROP) database[25] to explore tube feeding as a stroke intervention and its association with amount of therapy time and rehabilitation outcomes for patients with moderate or severe strokes. The PSROP database contains patient characteristics and process and outcome data for 1161 consecutively enrolled adult (>18y) stroke patients in 6 inpatient rehabilitation facilities across the United States. Stroke was defined as having an *International Classification of Diseases, 9th Revision* (ICD-9),[26] code of 430 to 438.99, 997.02, or 852 to 853 for the rehabilitation admission. Mild, moderate, and severe strokes were classified by case-mix groups (CMGs) of 100 to 103, 104 to 107, and 108 to 114, respectively. Patients with mild stroke were not included in the sample because of the low frequency of tube feeding (2.9%). In addition, patients with missing CMGs were not included. The PSROP sample was reduced from a total of 1161 to 919 patients, with 474 moderate strokes and 445 severe stroke patients who were discharged to home, the community, or a skilled nursing facility.[25]

Functional status was determined using total and component (motor, cognitive) FIM scores on admission and discharge. Severity of illness was measured for 3 time periods: admission (first 24h of rehabilitation), discharge (last 24h of rehabilitation), and maximum (entire rehabilitation stay including admission and discharge), as measured by the CSI based on signs and symptoms extracted from the medical record.

Tube-feeding data were abstracted from inpatient rehabilitation charts after patient discharge. Data abstractors entered the date of, type of, and reason for tube placement. Start and stop times of an enteral formula, amount, and delivery frequency were collected from physician orders. Based on those data, the 919-patient sample of moderate and severe stroke patients was divided into 4 tube-feeding groups: (1) no tube feeding (n=758); (2) tube feeding for less than 25% of the rehabilitation stay (n=17) with tube feeding discontinued before discharge; (3) tube feeding for 25% or more of the rehabilitation stay with tube feeding discontinued before discharge (n=109); and (4) tube feeding for 100% of stay and discharged on tube-feeding support (n=35). The last group was defined by the following criteria: (1) a patient's last ordered diet type was nothing by mouth or a speech and language pathologist was supervising all oral intake, (2) the patient was unable to swallow liquids or solids 24 hours before discharge, (3) a percutaneous endoscopic gastrostomy or other gastrostomy tube had been placed, and (4) the patient was discharged to a skilled nursing facility or home health agency. Group 4 patients never advanced to sufficient oral intake.

Patient Variables

Patient variables include sex; age; race; payer source; previous stroke; hypertension diagnosis; diabetes diagnosis; depression diagnosis; any other mental disorder diagnosis; body mass index (BMI) on admission (categorized as underweight [$<18.5 kg/m^2$], normal [$18.5–24.9 kg/m^2$], overweight [$25.0–29.0 kg/m^2$], obese [$\geq 30.0 kg/m^2$]); type, location, and side of stroke; number of days from onset of stroke symptoms to admission to rehabilitation; admission motor and cognitive FIM scores; admission CSI continuous scores; and nutritional risk. Higher FIM scores indicate higher functioning levels, and higher CSI scores indicate increased severity of illness, or sicker patients. Nutritional risk was defined by using the first serum albumin or prealbumin level measurement. A patient was considered to be at high nutritional risk if the first serum albumin level was less than 2.5g/dL or if the first prealbumin level was less than 15mg/dL, moderate risk if the first albumin level was 2.5 to 3.0g/dL or the first prealbumin level was 15 to 20g/dL, low risk if the first albumin level was 3.0 to 3.5g/dL or the first prealbumin level was 20 to 25mg/dL, or no risk if the first albumin level was greater than 3.5g/dL or the prealbumin level was greater than 25mg/dL.

Process Variables and Interventions

Process variables include inpatient rehabilitation LOS, tube feeding, and average number of therapy minutes per patient per day for PT, OT, and SLP sessions calculated by dividing the number of total minutes in each type of therapy by the LOS.

Outcome Variables

Primary outcome measures include improvements in functioning using the difference between admission and discharge total, motor, and cognitive FIM scores. Secondary outcome measures include improvements in severity of illness (CSI) from admission to discharge (net medical improvement), increase in severity of illness (CSI) from admission to maximum, change in weight from the first to last weight measurments, mental disorder diagnosis (ICD-9 codes starting with 781, 294, 305, 309, 310, 311), depression diagnosis (ICD-9 codes 311−311.99), pneumonia diagnosis (ICD-9 codes starting with 480−486, 507), and improvement in nutritional status, defined as a decrease in nutritional risk from the first to last measured albumin and/or prealbumin level. Larger differences in FIM score and net medical improvement (CSI) scores signify more recuperation. Larger increases in CSI from admission to maximum signify a worsening condition at some time during the rehabilitation stay. Discharge destination was not used as an outcome variable in regression analysis because it was used to define the group of patients discharged with tube feeding.

Statistical Methods

Descriptive statistics were used to compare patient characteristics, therapy interventions, and outcomes for the 4 tube-feeding groups, along with site variation in tube feeding and common nutrition assessment measures. Chi-square tests were

used for categoric data, and analysis of variance was used for continuous data.

Ordinary least squares (OLS) regression was used to identify associations between patient characteristics and the tube-feeding groups with continuous outcome variables. To avoid multicollinearity, only variables with a correlation coefficient less than .50 were allowed to enter regression models for patients with moderate and severe stroke. Stepwise selection was used at a significance level of .10 to allow independent variables to enter and leave each model. The final models were the most parsimonious, with the maximum number of variables with significance levels less than .05. All analyses were performed with SAS statistical software, release 8.2.[a]

RESULTS

To understand the associations of tube feeding with outcomes, we begin by assessing similarities and differences in patients with moderate (CMG 104–107) and severe (CMG 108–114) strokes who received tube feeding compared with those who did not.

Patient Variables

Patient characteristics by tube-feeding group are presented in table 1. Almost 6% of patients with moderate strokes and 30% of patients with severe strokes received tube feeding during rehabilitation.

Demographic and health plan characteristics. There were no significant differences in demographic characteristics for sex or age by tube-feeding groups for moderate or severe stroke patients. Racial differences were significant in the severe stroke group. Most patients discharged on tube-feeding support had Medicare insurance (60.0% and 73.3% for moderate and severe strokes, respectively).

Health and functional status characteristics. Nutritional risk, as defined by albumin/prealbumin level, varied significantly by tube-feeding group for patients with moderate and severe stroke ($P<.001$). Thirty-three percent of patients with moderate stroke and 38% of patients with severe stroke who received any tube feeding were at moderate or high nutritional risk. For patients at high nutritional risk, 73% with moderate strokes and 60% with severe strokes received no tube feeding during rehabilitation. Many patients who received tube feeding (44% with moderate stroke, 26% with severe stroke) had no albumin or prealbumin measurements taken during rehabilitation.

In the moderate stroke group, more patients who received tube feeding were overweight or obese (70.4%) compared with those without tube feeding (53.5%, $P<.001$). For the severe stroke group there were proportionately more overweight and obese patients in the non–tube-feeding group (59.8%) than in the tube-feeding group (54.5%) ($P=.035$).

Stroke risk factors and stroke type and side were not significantly different among tube-feeding groups. Most tube-fed patients with moderate strokes had brainstem/subcortical and lobar strokes ($P=.006$).

FIM and CSI. Patients who received tube feeding differed significantly in function and severity of illness from patients who did not receive tube feeding. Tube-fed patients with moderate and severe stroke had significantly lower admission total and cognitive FIM scores and higher CSI admission scores. In addition, patients with severe stroke also had lower admission motor FIM scores.

When examining criteria used to determine CSI severity of illness for the tube-feeding groups, we found that the most severe symptoms of dysphagia (unable to swallow solids or liquids) were associated with tube-feeding groups. That is, almost all patients who were tube fed were unable to swallow solids or liquids or had dysphagia "not otherwise specified." However, there were 31 patients with moderate stroke and 38 patients with severe stroke who were unable to swallow solids or liquids and were not tube fed (see table 1, Maximum CSI Indicator Dysphagia).

Process Variables

Process variables by tube-feeding group are presented in table 2.

Length of stay. Rehabilitation LOSs in tube-feeding groups differed for patients with moderate and severe stroke. For patients with moderate stroke, the mean LOS for patients who were discharged with tube-feeding support (16.8d) was closer to the mean of patients not tube fed (15.0d), both of which were less than that for patients who were tube fed for 1% to 24% and 25% or more of their stay (20d and 8.7d, respectively; $P=.079$). For patients with severe stroke, again the mean LOS for patients who were discharged with tube-feeding support (23.1) was closer to the mean LOS for patients not tube fed (23.6d), both of which were shorter than for patients who were tube fed for 1% to 24% and 25% or more of their stay (34.2, 28.7d, respectively; $P<.001$).

Therapy. For the moderate stroke group, tube feeding was not associated with the average number of days, total minutes, or minutes per patient per day spent in PT or OT sessions. However, for the severe stroke group, patients with tube feeding spent significantly fewer minutes per day in PT and OT compared with patients with no tube feeding ($P<.025$). For both stroke severity levels, SLP minutes per day were higher for patients receiving tube feeding, although the difference was significant for patients with moderate strokes only.

Outcome Variables

Outcome variables by tube-feeding group are presented in table 3.

Nutritional status. Significant differences in improvements in nutritional status (change in albumin or prealbumin levels from admission to discharge) for patients who did or did not receive tube feeding were found in the severe stroke group ($P=.022$). Patients with tube feeding showed more improvement.

Depression. We found that significantly more patients with moderate and severe stroke who were tube fed had a depression diagnosis, compared with patients without tube feeding ($P=.037$ vs $P=.047$, respectively).

Discharge FIM and CSI scores. At discharge, patients receiving tube feeding for 1% to 24% and 25% or more of their stay had similar discharge motor, cognitive, and total FIM scores as the non–tube-feeding group. However, these scores differed significantly from those of patients who were discharged on tube feeding ($P<.001$). Larger increases in FIM (total, motor, cognitive) scores were seen in the 2 tube-fed patient groups (tube fed for 1%–24% and ≥25% of stay); increases were significantly less for patients discharged on tube feeding. At discharge, patients receiving tube feeding for 1% to 24% and 25% or more of their stay had similar discharge CSI scores as the non–tube-feeding group. However, these scores were significantly lower than scores for patients who were discharged on tube feeding ($P<.001$).

Site Variation

We examined variation in tube-feeding interventions and nutritional assessment measures across the 6 facilities (table 4).

For patients with moderate stroke, the percentage of patients with tube feeding for 1% to 24% of stay varied little by site

Table 1: Patient Variables for Moderate and Severe Strokes by Tube-Feeding Group

Variables	Moderate Stroke (CMGs 104–107)					Severe Stroke (CMGs 108–114)				
	No Tube Feeding (n=447)	Tube Feeding 1%–24% of Stay (n=4)	Tube Feeding ≥25% of Stay (n=18)	Tube Feeding 100% of Stay; Discharged with Tube Feeding (n=5)	Variation Significance (*P*)	No Tube Feeding (n=311)	Tube Feeding 1%–24% of Stay (n=13)	Tube Feeding ≥25% of Stay (n=91)	Tube Feeding 100% of Stay; Discharged with Tube Feeding (n=30)	Variation Significance (*P*)
Demographics										
Male (%)	49.7	50.0	55.6	60.0	.931*	51.1	61.5	55.0	53.3	.829*
Age (y)	65.3±14.9	60.7±5.3	66.4±14.7	68.8±14.5	.861†	68.1±13.9	64.3±15.1	66.4±14.5	70.2±14.5	.428†
Race (%)					.342*					.023*
White	55.9	75.0	61.1	80.0		51.5	61.5	67.0	73.3	
Black	29.1	25.0	11.1	0.0		28.6	30.8	14.3	10.0	
Other	15.0	0.0	27.8	20.0		19.9	7.7	18.7	16.7	
Payer (%)					.015*					.008*
Medicare	54.6	25.0	66.7	60.0		64.6	23.1	56.0	73.3	
Medicaid	11.6	0.0	5.6	0.0		10.6	0.0	12.1	16.7	
Commercial	32.0	75.0	22.2	20.0		21.2	61.5	26.4	6.7	
Self-pay	1.3	0.0	0.0	20.0		2.6	15.4	4.4	3.3	
Unknown/missing	0.5	0.0	5.6	0.0		1.0	0.0	1.1	0.0	
Health and functional status characteristics										
Nutritional risk by first albumin/prealbumin level (%)					<.001*					<.001*
No nutritional risk	11.0	0.0	5.6	20.0		10.9	7.7	4.4	3.3	
Low nutritional risk	13.4	0.0	22.2	0.0		18.0	23.1	38.5	13.3	
Moderate nutritional risk	7.8	25.0	11.1	0.0		9.6	30.8	18.7	23.3	
High nutritional risk	3.6	0.0	22.2	40.0		10.9	7.7	17.6	20.0	
No albumin/prealbumin measurement	64.2	75.0	38.9	40.0		50.5	30.8	20.9	40.0	
BMI (%)					<.001*					.035*
Underweight (<18.5kg/m^2)	2.9	0.0	11.1	40.0		1.6	7.7	8.8	6.7	
Normal (18.5–24.9kg/m^2)	43.6	25.0	16.7	0.0		38.6	38.5	34.1	46.7	
Overweight (25–29kg/m^2)	32.9	25.0	61.1	60.0		36.3	38.5	40.7	40.0	
Obese (≥30kg/m^2)	20.8	50.0	11.1	0.0		23.5	15.4	16.5	6.7	
Stroke risk factors (%)										
Previous stroke (exclude TIA)	27.5	0.0	44.4	40.0	.224*	33.4	30.8	20.9	26.7	.141*
Hypertension diagnosis	77.4	75.0	72.2	80.0	.961*	83.6	76.9	81.3	76.7	.721*
Diabetes diagnosis	27.1	0.0	27.8	40.0	.590*	33.8	15.4	35.2	33.3	.564*
Type of stroke (%)					.314*					.042*
Hemorrhagic	21.5	50.0	16.7	0.0		24.4	46.2	35.2	16.7	
Ischemic	78.5	50.0	83.3	100.0		75.6	53.8	64.8	83.3	

Table 1: (Cont'd) Patient Variables for Moderate and Severe Strokes by Tube-Feeding Group

Variables	Moderate Stroke (CMGs 104–107)					Severe Stroke (CMGs 108–114)				
	No Tube Feeding (n=447)	Tube Feeding 1%–24% of Stay (n=4)	Tube Feeding ≥25% of Stay (n=18)	Tube Feeding 100% of Stay; Discharged with Tube Feeding (n=5)	Variation Significance (*P*)	No Tube Feeding (n=311)	Tube Feeding 1%–24% of Stay (n=13)	Tube Feeding ≥25% of Stay (n=91)	Tube Feeding 100% of Stay; Discharged with Tube Feeding (n=30)	Variation Significance (*P*)
Side of stroke (%)					.193*					.557*
Right	46.1	25.0	33.3	40.0		44.7	38.5	42.9	33.3	
Left	42.5	75.0	44.4	40.0		43.7	53.9	38.5	50.0	
Bilateral	8.7	0.0	22.2	0.0		9.0	7.7	16.5	16.7	
Unknown	2.7	0.0	0.0	20.0		2.6	0.0	2.2	0.0	
Location of stroke (%)					.006*					.447*
Brainstem/cerebellum	22.6	25.0	22.2	0.0		15.4	0.0	11.0	13.3	
Subcortical	34.0	0.0	27.8	20.0		43.7	53.9	36.3	33.3	
Brainstem + subcortical	4.5	50.0	16.7	0.0		3.2	7.7	5.5	0.0	
Lobar	33.8	25.0	33.3	60.0		32.5	38.5	41.8	50.0	
Unknown	5.2	0.0	0.0	20.0		5.1	0.0	5.5	3.3	
Days onset to rehabilitation admission	10.6±11.5	35.3±30.9	13.2±17.0	5.6±1.5	.002†	15.8±28.7	12.8±8.0	21.9±29.5	23.6±35.9	.186†
FIM										
Admission total FIM score	72.5±9.8	61.5±9.0	67.4±10.4	64.2±16.2	.006†	47.7±11.7	32.9±9.1	35.8±10.7	33.2±11.3	<.001†
Admission motor FIM score	48.0±5.6	42.5±1.0	47.9±5.8	46.2±7.2	.238†	29.0±6.4	21.3±5.3	22.6±6.6	22.3±7.7	<.001†
Admission cognitive FIM score	24.5±7.1	19.0±8.5	19.4±7.1	18.0±9.4	.002†	18.7±7.5	11.6±4.5	13.2±6.7	10.8±5.8	<.001†
CSI										
Maximum CSI indicator dysphagia (%)					<.001*					<.001*
Unable to swallow solids	6.0	25.0	22.2	20.0		7.7	15.4	17.6	6.7	
Unable to swallow liquids	0.9	25.0	38.9	80.0		4.5	38.5	52.8	90.0	
Dysphagia NOS	34.2	50.0	38.9	0.0		56.9	46.2	27.5	3.3	
Normal swallowing	30.2	0.0	0.0	0.0		11.3	0.0	1.1	0.0	
Unknown/missing	28.6	0.0	0.0	0.0		19.6	0.0	1.1	0.0	
Admission CSI continuous score	15.4±9.7	16.8±9.1	24.4±13.3	34.6±11.5	<.001†	22.4±12.0	28.5±13.4	35.6±14.7	43.0±17.3	<.001†
Maximum CSI continuous score	22.2±12.9	26.0±16.6	41.1±17.3	56.2±30.5	<.001†	34.3±19.4	47.4±23.0	52.5±20.7	59.9±21.8	<.001†

NOTE. Values are mean ± standard deviation (SD) unless otherwise indicated.
Abbreviations: NOS, not otherwise specified; TIA, transient ischemic attack.
*Chi-square test.
†Analysis of variance (ANOVA).

Table 2: Process Variables for Moderate and Severe Strokes by Tube-Feeding Group

Process Variables	Moderate Stroke (CMGs 104–107)					Severe Stroke (CMGs 108–114)				
	No Tube Feeding (n=447)	Tube Feeding 1%–24% of Stay (n=4)	Tube Feeding ≥25% of Stay (n=18)	Tube Feeding 100% of Stay; Discharged With Tube Feeding (n=5)	Variation Significance (P)	No Tube Feeding (n=311)	Tube Feeding 1%–24% of Stay (n=13)	Tube Feeding ≥25% of Stay (n=91)	Tube Feeding 100% of Stay; Discharged With Tube Feeding (n=30)	Variation Significance (P)
Rehabilitation LOS	15.0±7.1	20.0±5.4	18.7±8.5	16.8±5.5	.079*	23.6±9.3	34.2±13.5	28.7±12.1	23.1±11.4	<.001*
PT										
No. of days	10.6±6.0	16.3±3.3	13.1±7.3	12.6±5.4	.085*	16.8±8.1	20.3±12.3	19.7±10.7	15.6±8.2	.018*
No. of minutes	665±384	950±256	704±398	622±404	.491*	1065±576	1204±949	1140±741	862±451	.016*
No. of min/patient/day	44.3±16.7	49.4±17.3	36.6±15.4	36.4±22.4	.162*	44.1±13.7	35.3±18.2	39.1±14.6	39.0±14.4	.003*
OT										
No. of days	9.2±5.8	13.3±4.7	12.3±6.8	10.4±9.3	.077*	14.5±8.0	16.7±12.0	16.9±10.5	13.9±7.7	.098*
No. of minutes	603±389	860±254	670±354	603±606	.530*	958±585	1088±869	1018±735	826±526	.441*
No. of min/patient/day	39.5±17.7	44.3±15.9	35.0±15.3	30.7±22.9	.454*	39.8±16.1	32.0±21.1	35.0±15.9	35.6±13.8	.025*
SLP										
No. of days	7.8±6.2	13.5±4.5	13.7±6.1	11.0±3.2	<.001*	13.7±8.4	18.8±10.0	18.2±10.8	14.4±9.8	<.001*
No. of minutes	396±355	656±291	755±374	564±152	<.001*	749±530	1107±710	1024±687	755±550	<.001*
No. of min/patient/day	24.7±16.2	32.4±11.2	38.4±12.3	34.9±10.6	.004*	30.8±15.8	31.6±13.4	34.1±14.2	32.5±15.2	.384*

NOTE. Values are mean ± SD.
*ANOVA.

(0%–1.8%), whereas the number of those tube feeding for 25% or more of stay ranged from 0% to 20.3% of a site's patients ($P<.001$). The number of patients discharged with tube feeding was very small in all sites, with only 5 patients in total.

The percentage of patients with severe stroke, who received tube feeding was statistically different by site ($P<.001$). Approximately 65% of patients in site 5 received tube feeding compared with 13% to 27% for the other sites. Over 17% of site 5 patients were discharged with tube feeding, which was double the percentage of the site with the second highest percentage. It is important to note that patients in site 5 had the lowest average admission total FIM score (lowest functioning) and the highest maximum CSI score (highest severity of illness), and the site had the second largest percentage of patients with severe stroke.[25]

Nutritional assessment methods of monitoring serum albumin and serum prealbumin levels and weight varied significantly by site ($P<.001$ for each). For patients with moderate strokes, the percentage of patients with more than 1 albumin level measurement varied by site from 5.4% to 34.3%; the percentage with no serum albumin measurements ranged from 20.6% to 81.3%. For patients with severe strokes, the variation by site for no serum albumin measurements ranged from 7.3% to 77.3%. No serum prealbumin measurements were recorded at sites 2 and 5. The number of patients with moderate strokes who were weighed more than once varied by site from 54.8% to 91.5%; it varied from 73.9% to 95.6% for patients with severe strokes. Two sites weighed all patients with severe strokes at least once (range of no weight measurements, 0%–21.7%).

Regression Analyses

Patients who received tube feeding for their entire rehabilitation stay and were discharged with tube feeding (group 4) were not included in OLS regression analyses, because they did not advance to oral intake or progressed little in other rehabilitation outcomes, as shown in table 3.

Tables 5 and 6 present significant variables in OLS regression analyses to predict the outcomes of increase in total FIM, motor FIM, and cognitive FIM scores and net medical improvement for patients with moderate and severe stroke. Patient characteristics and rehabilitation LOSs were controlled for in all analyses. Tube feeding for 1% to 24% of stay had only a borderline positive association ($P=.08$) with an increase in total FIM score in the moderate-stroke group and was not significant for the other outcomes (see table 5). For patients with severe stroke, tube feeding for 25% or more of stay had a significant positive association with each outcome; tube feeding for 1% to 24% of stay had a significant positive association with increase in total FIM and motor FIM scores only (see table 6).

DISCUSSION

One of the most telling findings in our study is the large site variation in nutritional assessment measures and use of tube feeding, which indicate that clinicians differ in the importance they place on nutrition as a stoke rehabilitation intervention. Because low functioning and higher severity of illness are associated with increased rates of tube feeding in our data, it is not surprising that site 5 had more patients who received tube feeding. However, sites 1, 2, and 3 had a similar mix of severe strokes (40%–68%) as site 5 (51%) but did not use tube-feeding interventions as frequently.

There does not appear to be an association between sites that have more patients with tube feeding and the measuring of serum albumin and prealbumin levels, because many patients

Table 3: Outcome Variables for Moderate and Severe Strokes by Tube-Feeding Group

Outcome Variables	Moderate Stroke (CMGs 104–107)					Severe Stroke (CMGs 108–114)				
	No Tube Feeding (n=447)	Tube Feeding 1%–24% of Stay (n=4)	Tube Feeding ≥25% of Stay (n=18)	Tube Feeding 100% of Stay; Discharged With Tube Feeding (n=5)	Variation Significance (*P*)	No Tube Feeding (n=311)	Tube Feeding 1%–24% of Stay (n=13)	Tube Feeding ≥25% of Stay (n=91)	Tube Feeding 100% of Stay; Discharged With Tube Feeding (n=30)	Variation Significance (*P*)
Improvement in nutritional status based on first and last albumin/prealbumin levels (must have >1 serum albumin/prealbumin measurement) (%)	4.0	0.0	11.1	20.0	.163*	4.5	15.4	8.8	16.7	.022*
Any mental disorder diagnosis (%)	51.7	50.0	61.1	60.0	.862*	53.4	61.5	51.7	60.0	.809*
Depression diagnosis (%)	9.0	25.0	27.8	20.0	.037*	12.2	30.8	22.0	16.7	.047*
Weight change (last − first) (kg)	−0.3±4.4	2.6±7.1	−0.4±4.9	2.2±6.2	.389†	−1.8±6.1	−0.4±3.1	−0.8±4.4	−0.9±4.6	.444†
Discharge total FIM score	98.6±11.6	96.3±9.9	98.4±15.2	68.4±28.8	<.001†	77.2±19.3	78.0±11.2	69.9±23.2	47.6±21.4	<.001†
Increase in total FIM score (discharge − admission)	26.1±9.7	34.8±13.0	30.5±15.2	4.2±23.7	<.001†	29.4±14.4	45.1±12.6	33.9±20.3	14.7±15.7	<.001†
Discharge motor FIM score	70.4±8.8	70.3±10.0	73.1±12.6	49.6±22.2	<.001†	53.5±14.6	57.9±10.8	49.6±18.5	33.6±16.6	<.001†
Increase in motor FIM score (discharge − admission)	22.4±8.2	27.8±10.6	25.0±12.1	3.4±20.1	<.001†	24.5±12.3	36.6±13.0	26.9±16.8	11.7±13.1	<.001†
Discharge cognitive FIM score	28.2±5.9	26.0±7.4	25.1±6.1	18.8±10.0	<.001†	23.7±7.0	20.1±5.5	20.2±7.6	13.9±7.4	<.001†
Increase in cognitive FIM score (discharge − admission)	3.6±3.6	7.0±2.5	5.7±4.5	0.8±4.6	.009†	4.9±4.3	8.5±2.7	7.0±5.1	3.1±4.4	<.001†
Discharge CSI continuous score	5.5±6.3	6.25±2.6	10.8±6.8	26.4±13.8	<.001†	11.8±11.6	13.6±10.3	16.7±11.5	30.6±17.0	<.001†
Increase in severity (maximum − admission CSI score)	6.8±7.3	9.3±8.1	16.6±10.9	21.6±19.7	<.001†	11.9±11.4	18.8±18.3	16.8±12.4	16.9±13.7	.001†

Table 3: (Cont'd) Outcome Variables for Moderate and Severe Strokes by Tube-Feeding Group

Outcome Variables	Moderate Stroke (CMGs 104–107)					Severe Stroke (CMGs 108–114)				
	No Tube Feeding (n=447)	Tube Feeding 1%–24% of Stay (n=4)	Tube Feeding >25% of Stay (n=18)	Tube Feeding 100% of Stay; Discharged With Tube Feeding (n=5)	Variation Significance (*P*)	No Tube Feeding (n=311)	Tube Feeding 1%–24% of Stay (n=13)	Tube Feeding >25% of Stay (n=91)	Tube Feeding 100% of Stay; Discharged With Tube Feeding (n=30)	Variation Significance (*P*)
Net medical improvement (admission − discharge CSI score)	9.9±8.0	10.5±10.5	13.6±11.3	8.2±5.2	.282†	10.6±9.3	14.9±7.3	18.9±11.3	12.4±10.3	<.001†
Pneumonia diagnosis (%)	1.8	0.0	5.6	20.0	.028*	5.5	15.4	22.0	20.0	<.001*
Discharge destination (%)					.307*					<.001*
Community discharge including home	95.1	100.0	100.0	80.0		77.8	69.2	68.1	43.3	
Inpatient institutional discharge	4.9	0.0	0.0	20.0		22.2	30.8	31.9	56.7	

NOTE. Values are mean ± SD unless otherwise indicated.
*Chi-square test.
†ANOVA.

Table 4: Site Variation in Nutrition Process Variables

Facility Processes	Moderate Stroke (CMGs 104–107)							Severe Stroke (CMGs 108–114)						
	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	*P*	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	*P*
Patients (n)	73	91	47	112	59	92		82	66	119	46	91	41	
Enteral tube feeding (%)							<.001*							<.001*
No tube feeding	97.3	100.0	95.7	95.5	72.9	97.8		75.6	84.9	76.5	87.0	35.2	73.2	
Tube feeding 1%–24% of stay	1.4	0.0	0.0	1.8	1.7	0.0		4.9	3.0	2.5	2.2	2.2	2.4	
Tube feeding ≥25% of stay	1.4	0.0	4.3	0.9	20.3	2.2		18.3	9.1	16.8	2.2	45.1	19.5	
Tube feeding 100% of stay and discharged with tube feeding	0.0	0.0	0.0	1.8	5.1	0.0		1.2	3.0	4.2	8.7	17.6	4.9	
Serum albumin measurements (%)							<.001*							<.001*
0	20.6	73.6	72.3	81.3	44.1	78.3		7.3	77.3	54.6	54.4	31.9	56.1	
1	45.2	18.7	21.3	13.4	39.0	16.3		39.0	18.2	30.3	34.8	36.3	22.0	
>1	34.3	7.7	6.4	5.4	17.0	5.4		53.7	4.6	15.1	10.9	31.9	22.0	
Serum prealbumin measurements (%)							<.001*							<.001*
0	84.9	100.0	100.0	97.3	100.0	82.6		68.3	100.0	90.8	91.3	100	61.0	
1	13.7	0.0	0.0	2.7	0.0	15.2		29.3	0.0	7.6	8.7	0.0	22.0	
>1	1.4	0.0	0.0	0.0	0.0	2.2		2.4	0.0	1.7	0.0	0.0	17.1	
Weight measurements (%)							<.001*							<.001*
0	5.5	5.5	10.6	20.5	0.0	8.7		4.9	0.0	6.7	21.7	0.0	4.9	
1	39.7	14.3	29.8	13.4	8.5	23.9		17.1	4.6	24.4	4.4	4.4	19.5	
>1	54.8	80.2	59.6	66.1	91.5	67.4		78.1	95.5	68.9	73.9	95.6	75.6	
Mean no. of weight measurements ± SD	2.1±1.1	2.7±1.4	2.1±1.1	2.9±1.8	5.2±4.9	3.1±3.1	<.001†	2.7±1.2	4.6±2.1	2.7±1.5	3.5±1.8	8.7±7.6	4.1±4.0	<.001†

*Chi-square test.
†ANOVA.

Table 5: Improving Outcomes: Regression Analysis Results for Moderate Stroke (CMGs 104–107)*

	Dependent Variables											
	Increase Total FIM Score			Increase Motor FIM Score			Increase Cognitive FIM Score			Net Medical Improvement (Admission − Discharge CSI)		
Independent Variables	Coeff	F	*P*	Coeff	F	*P*	Coeff	F	*P*	Coeff	F	*P*
Tube feeding 1%–24% of stay	3.991	3.1	.080									
Partial R^2		.006										
Tube feeding ≥25% of stay												
Partial R^2												
Age	−0.174	35.5	<.001	−0.147	35.0	<.001	−0.020	4.5	.035			
White	1.774	4.3	.039	1.549	4.4	.036						
Other race										1.360	4.2	.042
Incomplete low paraplegia or worse/ complete hemiplegia	−3.605	4.6	.032				−1.386	6.5	.011			
Incomplete hemiplegia										3.073	22.9	<.001
Stroke location: brainstem/cerebellum										1.442	6.6	.010
Comorbidity diabetes							0.629	4.1	.043			
Admission motor FIM score	−0.493	37.0	<.001	−0.474	47.5	<.001						
Admission cognitive FIM score	−0.247	16.1	<.001				−0.307	224.0	<.001			
Admission CSI score							−0.039	7.1	.008	0.657	778.4	<.001
Rehabilitation LOS	−0.223	12.3	<.001	−0.225	17.8	<.001						
R^2		.186			.148			.357			.627	

Abbreviation: Coeff, coefficient.
*n=469.

with low albumin or prealbumin levels were not tube fed. Albumin and prealbumin values were obtained by retrospective chart review. A portion of site variability could be due to results not being reported clearly or documented in the chart at the time of review. In addition, other measures may have been used to assess nutritional risk, and clinicians may question whether high nutritional risk, as defined by low albumin or prealbumin level, is sufficient to initiate tube feeding. Studies

Table 6: Improving Outcomes: Regression Analysis Results for Severe Stroke (CMGs 108–114)*

	Dependent Variables											
	Increase Total FIM Score			Increase Motor FIM Score			Increase Cognitive FIM Score			Net Medical Improvement (Admission − Discharge CSI)		
Independent Variables	Coeff	F	*P*	Coeff	F	*P*	Coeff	F	*P*	Coeff	F	*P*
Tube feeding 1%–24% of stay	13.290	9.8	.002	12.225	12.1	.006						
Partial R^2		.013			.018							
Tube feeding ≥25% of stay	5.424	8.2	.005	4.497	8.4	.004	1.335	6.8	.009	3.567	11.0	.001
Partial R^2		.011			.013			.008			.012	
Age	−0.337	39.5	<.001	−0.332	55.3	<.001	−0.044	9.1	.003			
Incomplete low paraplegia or worse/complete hemiplegia	−9.127	20.8	<.001	−7.419	19.5	<.001				−2.997	7.8	.005
Incomplete hemiplegia												
Monoplegia UE/complete monoplegia LE/normal				4.902	4.4	.037						
Stroke type: hemorrhagic							−1.126	6.5	.011	2.262	6.2	.013
Stroke side: right							0.861	4.8	.029			
Stroke side: left				3.370	7.2	.008						
Comorbidity diabetes	−4.790	9.8	.002	−3.695	8.3	.004	−1.256	9.5	.002	−1.781	4.4	.038
BMI underweight (<18.5kg/m^2)										4.556	4.2	.042
Admission motor FIM score	0.249	4.4	.038				0.097	7.6	.006	0.187	6.6	.011
Admission cognitive FIM score				0.329	14.6	<.001	−0.288	87.1	<.001	0.136	4.7	.031
Admission CSI score							−0.044	6.7	.010	0.427	143.5	<.001
Rehabilitation LOS	0.210	7.6	.006				−1.344	6.5	.011	0.157	14.8	.001
R^2		.201			.206			.301			.405	

Abbreviations: LE, lower extremity; UE, upper extremity.
*n=415.

have shown that malnutrition is associated with poorer outcomes, so it would seem that nutrition and nutritional assessment measures would be a standard of care implemented with similar frequencies across not only hospital organizations but also in all other health care–providing institutions. However, in our sample of rehabilitation centers, this is not the case.

A possible reason for the disparity in tube feeding is the lack of data showing benefits of nutrition or tube feeding in stroke rehabilitation. Dávalos et al[3] found that nutritional status declined despite adequate enteral feeding after acute stroke. Dávalos concluded that caloric intake was not the only factor affecting malnutrition; therefore, the impact of nutritional intervention on stroke outcomes remained unclear.

Other articles suggest that the unclear relation may be due to the fact that serum albumin level, which usually is used in the definition of nutritional status, also is associated with underlying disease processes.[24,27] To minimize reliance on interpretation of albumin level, we related amount of tube feeding to rehabilitation outcomes directly. Tube feeding is associated with improved rehabilitation outcomes for patients with severe strokes, although not for patients with moderate strokes. One reason an effect may not have been detected in the moderate-stroke group is the small number of patients who received tube feeding—22 of 469 (4.7%) compared with 104 to 415 (25.1%) patients with severe stroke (omitting patients discharged with tube feeding). Intuitively, if tube feeding is beneficial for patients with severe strokes, it should be beneficial for patients with moderate strokes when deemed necessary by clinical staff.

One problem with tube feeding is the perceived risk of aspiration that may lead to mild symptoms, such as small increases in white blood cell count, higher temperatures, and lethargy or more severe symptoms associated with pneumonia.[28] These symptoms may decrease a patient's ability to participate fully in therapy, thus affecting outcomes. The challenge with assessing aspiration risk is knowing what caused the aspiration. Feeding tubes often are placed when patients are at risk for aspiration, but as their swallowing improves, they begin therapeutic oral feedings while continuing tube feeding. Our data were not collected in a manner that would allow us to differentiate reasons for aspiration in these types of patients, so the cause-and-effect association of tube feeding and aspiration would be difficult to interpret. This limits our ability to understand if the improvement in outcomes associated with tube-fed patients is related to nutrition or to the reduction of adverse aspiration signs and symptoms that negatively affect therapy. However, tube-fed patients with moderate and severe strokes did have a significantly larger increase in severity of illness (maximum and admission CSI) and did have a pneumonia diagnosis code significantly more often during rehabilitation than patients who were not tube fed. We did not determine if pneumonia was diagnosed before or after tube placement. The general rule is that sicker patients have poorer outcomes, but this did not hold in our sample. It appears that tube feeding provided enough of a benefit to counteract the negative effects of aspiration that may cause greater increase in severity of illness and more pneumonia, leading to the assumption that nutrition is an intervention that improves outcomes.

The PSROP provided a first look at how nutrition may be an important component of stroke rehabilitation. The primary objective of this article was to describe and test our hypothesis that nutrition risk assessment and use of tube feeding is associated with better outcomes for patients with moderate and severe strokes. Our data indicate that use of tube feeding is associated with greater increases in function and decreases in severity of illness for patients with severe strokes, but clearly further examination is warranted.

CONCLUSIONS

This study identifies nutritional support (tube feeding) as an effective therapy in stroke rehabilitation. Use of nutritional intervention was associated with greater motor and cognitive improvements in the most severely impaired patients. The high level of site variation in the use of nutritional assessments and interventions for patients with stroke speaks loudly to the need for additional study of the role of nutrition as an important component of stroke rehabilitation. Further study, including a consistent measure of nutritional status during the rehabilitation stay, seems warranted.

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ORIGINAL ARTICLE

The Early Impact of the Inpatient Rehabilitation Facility Prospective Payment System on Stroke Rehabilitation Case Mix, Practice Patterns, and Outcomes

Gerben DeJong, PhD, Susan D. Horn, PhD, Randall J. Smout, MS, David K. Ryser, MD

ABSTRACT. DeJong G, Horn SD, Smout RJ, Ryser DK. The early impact of the inpatient rehabilitation facility prospective payment system on stroke rehabilitation case mix, practice patterns, and outcomes. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S93-100.

Objective: To determine the early effects of the inpatient rehabilitation facility (IRF) prospective payment system (PPS) on stroke rehabilitation case mix, practice patterns, and outcomes.

Design: Prospective observational cohort study.

Setting: Three IRFs in the United States.

Participants: Consecutively enrolled convenience sample of 539 stroke rehabilitation patients treated between 2001 and 2003 in 3 IRFs.

Interventions: Not applicable.

Main Outcome Measures: Length of stay (LOS), therapy utilization, FIM instrument gain, and discharge destination.

Results: The IRF-PPS had no material short-term effect on stroke rehabilitation case mix and LOS for the study facilities. Facilities shifted physical and occupational therapy resources from those in the most severe case-mix groups (CMGs) to those in the moderate CMGs. Those in the more severe CMGs also experienced a noticeable decline in FIM score gain over the course of the rehabilitation stay. Using multivariate analyses, the authors discerned no major role for the IRF-PPS in explaining pre- and post-PPS differences in utilization and outcome among study facilities.

Conclusions: For the 3 study facilities, IRF-PPS did not materially reshape stroke rehabilitation case mix, utilization, and outcome in the early stages of PPS implementation, apart from the shift in therapy resources from more severely involved stroke patients to moderately involved patients. The study's findings are limited to 3 facilities, and a longer time horizon is needed to more fully determine the effects of the IRF-PPS.

Key Words: Prospective payment system; Rehabilitation.

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INPATIENT REHABILITATION FACILITIES (IRFs) are a major venue for poststroke rehabilitation, and patients with stroke are the second-largest group of people served by IRFs, accounting for nearly 20% of all IRF discharges.[1] For better or for worse, payment systems are major drivers of poststroke rehabilitation care. The largest payer for inpatient rehabilitation care remains the Medicare program. Medicare pays for 65% of all IRF-level stroke care in the United States (Sam Fleming, eRehabData.com, personal communication, August 2, 2005), and its payment systems shape access, utilization, and costs of IRF-level care. In 2002, the Centers for Medicare and Medicaid Services (CMS) implemented a prospective payment system (PPS) for IRFs. Using in-depth stroke rehabilitation data from 3 IRFs across the nation, this article provides a preliminary assessment of the early impact of the IRF-PPS on stroke rehabilitation case mix, practice patterns (ie, length of stay [LOS], service mix, intensity), and short-term outcomes (ie, functional status, discharge disposition).

Background

The IRF-PPS had been a long time in coming. When Congress initiated the Medicare diagnosis-related group (DRG)–based PPS for short-stay acute care hospitals in 1983, it exempted specialty hospitals (ie, rehabilitation centers, children's hospitals, psychiatric hospitals, long-term care hospitals) and various postacute venues (eg, skilled nursing facilities [SNFs], home health agencies) from a PPS. Congress left these facilities to be paid on a modified cost basis as provided by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). Both Medicare DRGs and cost-based reimbursement for postacute care led to a rapid expansion of postacute facilities of all types from the mid 1980s to the mid 1990s. In 1997, Congress passed the Balanced Budget Act of 1997 to curb this growth by authorizing the Health Care Financing Administration to establish PPSs for IRFs, SNFs, and home health agencies. Congress later authorized a PPS for long-term care hospitals in the Balanced Budget Refinement Act of 1999 (BBRA 1999). When implementing these legislative mandates, CMS instituted different PPS methods for each postacute setting with different start dates and phase-in periods.

This article examines the early impact of the IRF-PPS on stroke rehabilitation patients, practices, and outcomes. More specifically, it examines the impact on stroke case mix (patient severity, case-mix groups [CMGs]); functional status; severity index; utilization (ie, LOS); the mix, duration, and intensity of therapy services; and outcomes at discharge (ie, functional status, discharge destination). It does not attempt to evaluate the indirect effects of other postacute PPSs on IRF-based stroke rehabilitation. Other postacute PPSs shape the willingness of various postacute providers to enter or exit the stroke rehabilitation market and their willingness to accept certain types of patients and thus indirectly shape the case-mix and practice patterns observed among IRFs. At this early stage, we do not have a clear picture of how the IRF-PPS is shaping stroke rehabilitation care and its

Table 1: Stroke CMGs and CMG Groupings by Relative Tier Weights

Stroke CMG Groupings	CMG	Stroke CMG Definition			Relative Weights			
		Motor FIM Score	Cognitive FIM Score	Age (y)	Tier 1	Tier 2	Tier 3	None
Mild (CMG 101–103)	0101	69–84	23–35		0.478	0.428	0.408	0.386
	0102	59–68	23–35		0.651	0.583	0.555	0.526
	0103	59–84	5–22		0.830	0.743	0.708	0.670
Moderate (CMG 104–107)	0104	53–58			0.901	0.807	0.769	0.728
	0105	47–52			1.134	1.016	0.968	0.916
	0106	42–46			1.395	1.249	1.191	1.127
	0107	39–41			1.616	1.447	1.379	1.305
Severe (CMG 108–114)	0108	34–38		≥83	1.748	1.565	1.492	1.412
	0109	34–38		<83	1.890	1.693	1.613	1.527
	0110	12–33		≥89	2.028	1.816	1.730	1.638
	0111	27–33		82–88	2.089	1.871	1.783	1.687
	0112	12–26		82–88	2.478	2.220	2.115	2.002
	0113	27–33		<82	2.238	2.004	1.910	1.807
	0114	12–26		<82	2.730	2.445	2.330	2.205

Source: Centers for Medicare and Medicaid Services.[6]

outcomes. We do know anecdotally that many IRFs have made adjustments in their programs in the wake of the IRF-PPS, but we do not know how they have adjusted their programs and the effects that these adjustments may have had on the nature of stroke care and its outcomes.

Design of the IRF-PPS

CMS initially sought to implement a per diem PPS known as resource utilization groups for IRFs as it had in the SNF industry. Instead, with the passage of the BBRA 1999, the IRF industry prevailed on Congress to have CMS implement a per-discharge PPS known as function-related groups (FRGs) based on each patient's functional profile on admission to rehabilitation. In other words, Medicare would pay IRFs a fixed amount per discharge or per case based mainly on each patient's functional status at admission.

The FRG approach was originally developed by Stineman et al[2] with industry backing in the early to mid 1990s. Using rehabilitation LOS as a proxy for resource utilization, Stineman attempted to determine for each impairment group, such as stroke, those patient characteristics (eg, functional status [as measured by the FIM instrument], age) that best explained variation in LOS. Based on the results of this work, the initial FRG system classified rehabilitation patients into 1 of 53 distinct groups according to each patient's impairment (eg, stroke), functional status (eg, FIM motor score), and—in some instances—age. Subsequent refinements undertaken by Stineman et al,[3] the Rand Corporation,[1,4,5] and CMS[6] eventually led to a 95-group classification system now referred to as CMGs. At the time of this study, there were 14 CMGs for stroke rehabilitation based on a patient's motor or cognitive FIM scores on admission, and in 7 CMGs, the patient's age is also taken into account (table 1).[7]

One of the later additions to the patient classification system for the IRF-PPS was an adjustment for comorbidities. Providers argued that their patients presented a host of comorbidities that affected resource utilization, as did each patient's functional status. In short, they argued that the function-based classification system overlooked the medical acuity and comorbidities that also drive resource utilization. The Health Care Financing Administration (now CMS) responded and had its principal contractor, Rand, take another look. Rand found that adding comorbidities did help explain additional variance in resource utilization. The final rule implementing the new PPS ranks each comorbidity according to 1 of 3 tiers of severity specific to each patient's main impairment (eg, stroke). Thus, each CMG comes with 4 weights—3 for different levels of comorbidity severity and a fourth for no comorbidities.[6] The CMG weight assigned to each patient depends on the most severe comorbidity the patient presents. Although comorbidities are factored into the new PPS, there is uncertainty, if not controversy, about the current approach used to capture this dimension of patient need.

In addition to the function-based and comorbidity-modified patient classification system, the IRF-PPS also makes adjustments for (1) transfers—patients who are transferred from an IRF to other settings of care, (2) outliers—patients who have exceptionally long LOSs, and (3) interrupted stays—patients whose stay in an IRF is interrupted because of an acute condition that may require a temporary stay in an acute care hospital.

The IRF-PPS also makes adjustments in the per-case payment amount for market- and facility-level characteristics: (1) local wage rates—the payment system adjusts for the relative cost of labor in a given metropolitan statistical area; (2) rural status—the payment system provides an additional 19.14% payment for IRFs located in rural areas; and (3) low-income patient adjustment—the payment system provides additional payment for IRFs serving a disproportionate number of low-income patients.

Before these adjustments, the base rate for an average case in fiscal year 2004 was $12,525. In CMS parlance, this is known as the "conversion factor"—that is, the factor that is converted to a payment amount based on CMG-comorbidity weight, local wage adjustment, rural status, and low-income adjustment.

Impact of the IRF-PPS

Although considerable research work has been expended on the design of the IRF-PPS, comparatively little research has been published on the probable or actual impact of the IRF-PPS on access, case mix, utilization, costs, outcomes, and other issues such as provider equity, efficiency, financial performance, and gaming. Before IRF-PPS implementation, considerable work was done by both researchers and providers to estimate the probable financial impact of the IRF-PPS using simulation analyses and other techniques.[8] The chief limitation of this work is that investigators assumed that provider behav-

Table 2: Study Group Enrollment Pre- and Post-PPS

IRF	Pre-PPS	Post-PPS	Total*
A	79	78	157
B	58	133	191
C	98	93	191
Total	235	304	539

*Of the 567 patients, 28 had insufficient data (eg, incomplete FIM data) to assign them to a CMG. Thus, the total enrollment for purposes of this analysis is 539 patients.

ior would remain constant and that case-mix and practice patterns would therefore remain static.

It will be years before the many direct and indirect effects of the IRF-PPS on stroke rehabilitation can be fully observed, as we have learned from the implementation of the DRG-based PPS for short-term acute care hospitals. Providers will continue to make adjustments in stroke rehabilitation as they learn from their experiences during the first several years of implementation. Given the IRF-PPS implementation in 2002, there has been little time to report the new payment's impacts. This article provides an early window into the ways in which a geographically diverse group of 3 stroke rehabilitation providers have altered their case-mix and practice patterns and how these have affected utilization and short-term outcomes.

METHODS

The methodology governing the full PSROP, provided in this supplement by Gassaway et al,[9] provides a detailed description of the larger study's participating facilities, patient selection criteria, data collection instruments including their validity and reliability, and a detailed description of the project's final study group. The methodology is summarized in by Maulden et al.[10] The institutional review boards at Boston University and at each participating IRF approved the study.

Methods That Pertain to the Analysis of the Impact of the IRF-PPS

The PSROP offers a rare opportunity to examine the early impacts of the IRF-PPS, because patients were enrolled both before and after the implementation of the IRF-PPS in 2002. Three of the 6 facilities enrolled a substantial number of patients with stroke both before and after the implementation of the IRF-PPS. Hence, this analysis is limited to just these 3 facilities. The other 3 facilities enrolled patients predominately before or after the implementation of the IRF-PPS and we chose to exclude these facilities because they did not provide an adequate before-and-after view of how the case mix, practice patterns, and outcomes changed with the implementation of the IRF-PPS at these facilities.

Table 2 outlines the study group size and enrollment before and after the implementation of the IRF-PPS at each of the 3 facilities. These 3 facilities enrolled 567 stroke rehabilitation patients. Of this number, 28 patients had some missing FIM data and therefore could not be classified into 1 of the 14 stroke CMGs. We excluded these 28 patients, leaving a total of 539 patients included in this analysis (see table 2).

The 3 IRF facilities provide some geographic diversity—1 on the East Coast, 1 on the West Coast, and 1 in the middle of the United States. All 3 facilities were rehabilitation units in academic health centers.

Pre- and Post-PPS Periods

The IRF-PPS sought to bring greater equity among IRFs that previously had received widely varying levels of reimbursement under the old TEFRA system and to foster access for potential rehabilitation patients by tailoring the amount of payment to the functional and medical needs of each patient. In presenting our results below, we compare findings in the post-PPS period with those from the pre-PPS period. All 3 IRFs also had a ramp-up period before the IRF-PPS implementation date. This ramp-up period varied from 1 to 6 months. We speculated that IRF behavior with respect to admissions and processes of care might already have started to change during this ramp-up period. Accordingly, we considered 3 time periods for analyses: (1) a pre-PPS period, (2) a post-PPS period, and (3) a practice period in preparing for the IRF-PPS implementation. On closer examination of the data, we determined that nearly all patient and practice parameters during the practice or ramp-up period were nearly the same as those during the pre-PPS period and that the most marked changes, where they were discernable, occurred with the implementation of the PPS—that is, during the post-PPS period. Thus, we folded the ramp-up or practice period into the pre-PPS period and present our results below for only 2 periods, the pre-PPS period and the post-PPS period.

Medicare and Non-Medicare

The IRF-PPS applies only to stroke patients with Medicare and not to patients covered by other types of health plans. Medicare is the major driver of rehabilitation practice and its requirements and effects are known to spill over to patients covered by other health plans. We tested for Medicare and non-Medicare differences with respect to practice patterns and did not detect sufficient differences to exclude non-Medicare patients from the analyses presented below.

Two-Way, 3-Way, and Multivariate Analyses

In the results that follow, we examine the changes—pre- and post-PPS—across study group characteristics, medical and functional status, service utilization, and outcomes. In most instances, we added a third dimension to the analyses when examining changes from pre- to post-PPS—namely, the CMG groupings—to help account for case-mix differences. To simplify matters, we grouped patients into mild, moderate, and severe groupings (table 1).

Even in 2-way and 3-way analyses, there may be differences that can be explained only when all potential independent variables are considered concurrently. Thus, we used both ordinary least-squares (OLS) and logistic regression analyses to help explain differences in utilization and outcomes in the pre- and post-PPS periods. We sought to control for patient differences to determine how much of the variance could be explained by the IRF-PPS. We used a stepwise procedure that ceased when no other variables met the .08 level of significance for entry into the model.

One of the challenges in the regression analyses was how to capture the IRF-PPS in our regression models. We took 2 approaches. First, we used a simple dichotomous pre- and post-PPS variable. Second, we considered each facility's TEFRA limit before PPS. We hypothesized that the effect of the IRF-PPS on utilization and outcome would, in part, be a function of the IRF's pre-PPS TEFRA limit—that is, we had to take into account how high or how low the TEFRA limit was relative to the expected payment under PPS. To do so, we adjusted each facility's TEFRA limit by the CMS wage index to account for differences in labor purchasing power across market areas. We applied the CMS wage index to both the labor share of the TEFRA limit and to the entire TEFRA limit, and in both cases, the results were essentially the same: 1

Table 3: Study Group Characteristics Pre- and Post-PPS Enrollment

Patient Characteristics	Pre-PPS (n=235)	Post-PPS (n=304)	Total* (N=539)	P
Mean age (y)	66.0	65.7	65.8	.828†
Sex (% male)	50.6	50.7	50.7	1.00‡
Race (%)				.214‡
White	60.1	62.2	61.2	
Black	26.8	21.1	23.6	
Other (including Hispanic)	13.2	16.8	15.2	
Payer (%)				.016‡
Medicare	51.9	55.3	53.8	
Other	48.1	42.8	45.1	
Unknown or missing		2.0	1.1	
Type of stroke (%)				.479‡
Hemorrhagic	22.6	25.3	24.1	
Ischemic	77.5	74.7	75.9	
Mean admission FIM score	62.4	61.0	61.6	.465†
CMG (%)				.093‡
Mild (CMG 101–103)	8.1	13.8	11.3	
Moderate (CMG 104–107)	49.4	43.8	46.2	
Severe (CMG 108–114)	42.6	42.4	42.5	
CMI	1.39	1.42	1.41	.613†
Mean admission CSI§	20.1	21.9	21.1	.142†
Mean days from stroke onset to rehabilitation	10.9	10.7	10.7	.822†

Abbreviation: CMI, case-mix index.
*Of the 567 patients, 28 had insufficient data (eg, incomplete FIM data) to assign them to a CMG. Thus, the total enrollment for purposes of this analysis is 539 patients.
†The *t* test.
‡Chi-square test.
§Comprehensive Severity Index (CSI) expressed here as a continuous variable.

facility had a high adjusted TEFRA limit and 2 of the facilities had low adjusted TEFRA limits relative to their expected payment under PPS. In our model, we hypothesized that facilities having a high adjusted TEFRA limit, for example, had the financial wherewithal to provide a richer mix of therapy, offer longer LOSs, and with additional inputs, produce better outcomes in the pre-PPS period.

RESULTS

Study Group Characteristics and Impact on Stroke Case Mix

Table 3 describes the 3-facility study group's principal characteristics in terms of age, sex, race, type of stroke, payer mix, and each group's medical and functional profile. By tailoring the level of payment to the functional status and medical complexity of each patient with stroke on admission, the IRF-PPS was designed to encourage IRFs to admit patients based on the functional and medical needs of each patient with stroke. The old pre-PPS, it was thought, encouraged IRFs to admit less complex patients to maximize financial margins.

There are 2 ways to examine whether the IRF-PPS encouraged the 3 IRFs to admit patients with stroke with greater functional needs. The first is to examine pre- and post-PPS functional status, as measured by the FIM score at admission. We found that the 3 IRFs combined admitted only marginally more functionally dependent patients with stroke as measured by FIM score at admission. The second is to consider the pre- and post-PPS case-mix distributions by CMG. In this case, we grouped the stroke CMGs into mild (CMG 101–103), moderate (CMG 104–107), and severe (CMG 108–114) groups. Among the 3 facilities represented here, there was a modest shift from the moderate CMG group to the mild CMG group, and the percentage of those in the severe group remained about the same at about 42.5%.

One way to examine whether the IRF-PPS encouraged the 3 IRFs to admit those patients with stroke who had more complex medical needs is to evaluate the pre- and post-PPS patient scores on the Comprehensive Severity Index (the continuous version) at admission. We found that the 3 facilities served a slightly more (but statistically insignificant) medically complex group of patients with stroke in the post-PPS period than they did in the pre-PPS period.

A facility's case-mix index (CMI) captures, to some degree, both the functional and medical needs of its patients by considering each patient's CMG assignment (CMG 101–114) and each patient's tier level assignment within each CMG that takes into account the presumed severity of that patient's comorbidities. Both a patient's CMG assignment and tier assignment determine that patient's case weight (see table 1). Averaging all patient case weights determines a facility's or group's CMI, with a higher CMI indicating a more severe case mix. For the study group representing all 3 facilities, we found the CMI relatively unchanged from the pre-PPS period (CMI=1.39) to the post-PPS period

Table 4: Mean LOS by Stroke CMG Pre- and Post-PPS

Stroke CMG	Pre-PPS (d)	Post-PPS (d)	Change (d)	P*
Mild (CMG 101–103)	7.1	7.8	0.7	.665
Moderate (CMG 104–107)	13.5	14.9	1.4	.158
Severe (CMG 108–114)	25.2	24.1	−1.1	.496
Total	17.9	17.8	−0.1	.909

*The *t* test.

Table 5: Amount of Rehabilitation Therapy Received by Stroke CMG Pre- and Post-PPS

Therapy by Stroke CMG	Pre-PPS	Post-PPS	Change	P*
PT				
Mild (CMG 101–103)				
Mean min of PT	289.7	267.9	−21.8	.716
Mean LOS (d)	7.1	7.8	0.7	.665
Mean days of PT	5.0	4.8	0.2	.870
Mean min of PT/d	45.2	35.1	−10.1	.084
Moderate (CMG 104–107)				
Mean min of PT	547.7	645.0	97.3	.072
Mean LOS (d)	13.5	14.8	1.3	.158
Mean days of PT	8.3	10.0	1.7	.031
Mean min of PT/d	39.8	43.4	3.6	.160
Severe (CMG 108–114)				
Mean min of PT	1086.0	894.2	−191.8	.017
Mean LOS (d)	25.2	24.1	−1.1	.496
Mean days of PT	17.2	15.6	−1.6	.214
Mean min of PT/d	42.2	37.5	−4.7	.027
Total				
Mean min of PT	755.8	698.7	−57.1	.240
Mean LOS (d)	17.9	17.8	−0.1	.909
Mean days of PT	11.8	11.7	−0.1	.882
Mean min of PT/d	41.3	39.7	−1.6	.336
OT				
Mild (CMG 101–103)				
Mean min of OT	207.4	259.9	52.5	.428
Mean LOS (d)	7.1	7.8	0.7	.665
Mean days of OT	3.7	4.2	0.5	.672
Mean min of OT/d	28.8	34.8	6.0	.240
Moderate (CMG 104–107)				
Mean min of OT	474.3	568.1	93.8	.067
Mean LOS (d)	13.5	14.8	1.3	.158
Mean days of OT	7.1	8.7	1.6	.033
Mean min of OT/d	34.7	36.3	1.6	.498
Severe (CMG 108–114)				
Mean min of OT	986.2	782.1	−204.1	.009
Mean LOS (d)	25.2	24.1	−1.1	.496
Mean days of OT	15.2	13.6	−1.6	.198
Mean min of OT/d	38.3	33.3	−5.0	.019
Total				
Mean min of OT	670.5	616.3	−54.2	.243
Mean LOS (d)	17.9	17.8	−0.1	.909
Mean days of OT	10.3	10.2	−0.1	.918
Mean min of OT/d	35.8	34.8	−1.0	.531

*The *t* test.

(CMI=1.42). We also found little change within each of the 3 facilities represented in the study.

Impact on the Utilization and Provision of Stroke Rehabilitation Services

The IRF-PPS provides incentives for IRFs to review their practice patterns and processes of care relative to the resources that will be available for each stroke patient given their CMGs and tier assignments. To ascertain the steps taken at each facility with respect to the process of care, we queried each facility's lead stroke physician. They reported that they made no changes in admission criteria nor did they attempt to achieve a particular case mix. This is confirmed by the results noted above. The stroke physicians reported that they did not establish target LOSs based on PPS apart from the way in which they had always estimated expected LOS in the pre-PPS period. A couple reported that the projected LOS for each CMG gave them an additional benchmark by which to estimate an expected LOS. The 3 facilities already had formal or informal clinical pathways for stroke rehabilitation and did not revisit them in the wake of the IRF-PPS implementation. As a result, they reported no deliberate attempt to alter therapy frequency or intensity.

This said, the facilities reported that they did take steps to evaluate certain care processes, particularly at the front and back ends of a patient's stay. If they had not already done so, facilities sought to shorten the evaluation and assessment processes to make sure that therapy commenced more quickly and by day 2 whenever possible. At the back end, a patient's discharge can sometimes be delayed, for example, because of lack of equipment or arrangements at the target destination. Facilities reported that they made attempts to regularly review potential barriers to discharge and to address these barriers well in advance of the projected discharge date. In short, our respondents indicated that the changes were more administrative than clinical.

Table 6: Change in Functional Status from Admission to Discharge, Pre- and Post-PPS

Stroke CMG	Pre-PPS	Post-PPS	Change	P*
Mild (CMG 101–103)				
Admission FIM	94.7	89.3	−5.4	.039
Discharge FIM	108.7	109.1	0.4	.880
Increase in FIM	14.0	19.8	5.8	.015
Moderate (CMG 104–107)				
Admission FIM	72.4	71.5	−0.9	.503
Discharge FIM	99.8	96.9	−2.9	.090
Increase in FIM	27.3	25.4	−1.9	.231
Severe (CMG 108–114)				
Admission FIM	44.6	41.1	−3.5	.033
Discharge FIM	78.7	69.3	−9.4	.033
Increase in FIM	33.3	28.2	−5.1	.049
Total				
Admission FIM	62.4	61.0	−1.4	.465
Discharge FIM	91.8	87.0	−4.8	.015
Increase in FIM	28.7	25.8	−2.9	.034

*The *t* test.

Impact on LOS

For the 3 facilities combined, there was virtually no change in overall LOS from the pre- to the post-PPS period. The only marked change was at 1 facility that saw a 3-day decline in LOS, in part due to an increase in patients in the mild CMG group (101–103). Table 4 provides a breakdown in the changes in LOS by CMG. The largest increase, although not statistically significant, in LOS was among patients in the moderate CMG group. As observed in the next section, this group also had the largest increase in therapy time.

Impact on the Amount, Intensity, and Duration of Physical and Occupational Therapy Services

Table 5 characterizes the amount, duration, and intensity of therapy rendered. We could not report utilization of speech and language therapy because of incomplete data at one of the 3 facilities. We found that the 3 facilities provided somewhat less physical therapy (PT) and occupational therapy (OT) from the pre- to the post-PPS periods but not to any statistically significant degree.

More important is the very noticeable shift in both PT and OT services from those in the more severe CMGs (108–114) to those in the moderate CMGs (104–107). This is the opposite of what was intended under the IRF-PPS, which seeks to provide a more level playing field across all patients by tailoring the amount of payment to the medical and functional needs of each individual patient. Clearly, this is not case here, where we see a shift in resources from more severely impaired patients to more moderately impaired patients. This finding is what one would have expected under the old TEFRA payment system, where a fixed payment ceiling for all patients accompanied by a bonus payment for staying under the ceiling would clearly favor less-impaired patients. This shift in resources is also evident in the decreased LOSs for those in severe CMGs and the increased LOSs among those in the moderate CMGs.

We also tested the observation made by facility representatives that facilities achieved efficiencies by reducing the number of days spent on assessment and evaluation activities or days resulting from administrative barriers to discharge. The mean days spent in therapy declined directly with reduced

Table 7: Discharge Destination by Stroke CMG Pre- and Post-PPS

Stroke CMG	Discharge Destination	Pre-PPS (%)	Post-PPS (%)	Change (%)	P*
Mild (CMG 101–103)					.546
	Community	100.0	92.3	−7.1	
	Institution	0.0	7.1	7.1	
	Died	0.0	0.0	0.0	
Moderate (CMG 104–107)					.452
	Community	94.8	91.7	−3.1	
	Institution	5.2	8.3	3.1	
	Died	0.0	0.0	0.0	
Severe (CMG 108–114)					.948
	Community	64.0	62.0	−2.0	
	Institution	34.0	35.7	1.7	
	Died	2.0	2.3	0.3	
Total					.709
	Community	82.1	79.3	−2.8	
	Institution	17.0	19.7	2.7	
	Died	0.9	1.0	0.1	

*The chi-square test.

Table 8: OLS Regressions for Stroke Rehabilitation Utilization (n=534)

	Stroke Rehabilitation Utilization								
	LOS			Total PT and OT (min)			PT and OT (min/d)		
Independent Variables	Coeff	F	P	Coeff	F	P	Coeff	F	P
Sex (female)	−1.968	6.92	.009	−164.524	4.44	.036			
Admission motor FIM score	−0.424	192.52	<.001	−36.335	132.09	<.001			
Admission cognitive FIM score				9.929	3.33	.069	0.625	16.15	<.001
Admission CSI	0.063	4.01	.046						
Mild (CMG 101–103)							−8.554	4.24	.040
		R^2=.385			R^2=.236			R^2=.032	

Abbreviation: Coeff, coefficient.

LOS, and the number of non-PT or non-OT days did not decline as anticipated (see table 5).

Impact on Outcomes

Functional status at discharge. Table 6 provides a glimpse of the changes in functional outcomes at discharge. We found that overall, FIM scores at discharge and FIM score increase from admission to discharge declined somewhat from the pre- to post-PPS periods. However, these overall changes mask some of the changes among CMG groupings. Patients in the mild CMG grouping showed greater functional gains from the pre- to the post-PPS periods, whereas those in the moderate and severe CMG groupings showed a decline in functional gains from the pre- to post-PPS periods. A closer examination from facility to facility also showed some noticeable changes in the amount of functional gain across the 3 CMG groupings. The CMG subgroups become too small at the individual facility level to make any authoritative observations, except to note that observations in 1 facility tend to be cancelled out by another; thus, generalizations are difficult to make apart from these broader observations.

Discharge disposition. Overall, the percentage of patients with stroke discharged to home or to another community setting declined from 82.1% in the pre-PPS period to 79.3% in the post-PPS period, although the decline is not statistically significant. Table 7 indicates that the decline in discharge to a community setting occurred across all 3 CMG groupings. A closer facility-by-facility examination of the data uncovered no facilities that might have had a disproportionate impact on discharge disposition.

Multivariate analysis. Table 8 presents the results from the OLS regression analysis for 3 measures of stroke rehabilitation utilization—LOS, total amount of PT and OT (measured in minutes), and intensity of therapy as measured by the minutes of therapy per day. We found that we could explain at best up to 38.5% of the variance in utilization. None of the PPS variables entered any of the 3 regression models. Table 9 presents the results for the OLS regression analysis for the change in FIM and the logistic regression analysis for discharge disposition. Again, the PPS-related variables were not major variables that explain utilization and played a secondary role in explaining the increase in FIM score.

DISCUSSION

This study provides an in-depth view of how 3 IRFs responded to the IRF-PPS in the short term. We conclude that, for these 3 facilities, the IRF-PPS did not materially reshape stroke rehabilitation case mix, utilization, and outcome in the early stages of PPS implementation, apart from the shift in therapy resources from more severely impaired patients with stroke to moderately impaired patients. The study's 3 IRFs reported that they made several administrative adjustments in how patients were processed to achieve greater efficiencies and reduce the number of nontherapy days, but this observation is not borne out in the utilization and outcome data reported here. The IRFs did, of course, have to train staff to comply with the new payment system's reporting requirements. We did observe some facility-to-facility variations that pretty much cancelled each other out when examining the effects on the entire study group or within similar CMGs. The results of this study do not support the notion that providers would reduce services overall, although we did detect some shifts in resources among patient groups.

This study's chief advantage is that it provides detailed information about the amount of therapy services received relative to the medical and functional status of each patient with stroke during an important juncture in postacute payment

Table 9: OLS and Logistic Regressions for Stroke Rehabilitation Outcomes (n=534)

	Stroke Rehabilitation Outcomes					
	Increase in FIM			Discharge to Community		
Independent Variables	Coefficient	F	P	Estimate	Wald χ^2	P
Age	−0.314	59.68	<.001			
Race (white)	4.456	12.02	<.001			
Admission motor FIM score	−0.455	65.21	<.001	.048	13.67	<.001
Admission cognitive FIM score	−0.175	3.55	.060	.046	7.01	.008
Admission CSI	−0.222	15.08	.001			
Pre-PPS, high-TEFRA IRF	4.297	3.96	.047			
Moderate (CMG 104–107)	3.699	7.26	.007	.688*	3.54	.060
		R^2=.211			c=.794	

*Odds ratio point estimate: 1.99; 95% confidence limits, 0.97–4.08.

policy. The study's chief limitation, however, is that it examines the effects of the IRF-PPS among only 3 facilities. Although geographically diverse, we can make no claims as to the representativeness of these facilities relative to the 1200 IRFs in the United States.

CONCLUSIONS

In examining the effects of the IRF-PPS, we need to observe changes over a much longer period of time. There is a learning curve associated with every new payment and policy change, and it could be argued that the 3 IRFs represented in this study were still at the beginning stages of the learning curve. Nonetheless, providers generally are acutely aware of how payment systems affect their fiscal well-being. During the ramp-up period for the IRF-PPS, both the IRF industry and individual facilities conducted simulation analyses to determine how they would fare under the new payment system, given industry-wide and facility case mixes. Although individual facilities made numerous preparations for the implementation of the IRF-PPS, these preparations do not appear to have materially reshaped clinical practice in the short-run apart from the shifts observed in this analysis.

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ORIGINAL ARTICLE

Stroke Rehabilitation Patients, Practice, and Outcomes: Is Earlier and More Aggressive Therapy Better?

Susan D. Horn, PhD, Gerben DeJong, PhD, Randall J. Smout, MS, Julie Gassaway, MS, RN, Roberta James, MStat, Brendan Conroy, MD

ABSTRACT. Horn SD, DeJong G, Smout RJ, Gassaway J, James R, Conroy B. Stroke rehabilitation patients, practice, and outcomes: is earlier and more aggressive therapy better? Arch Phys Med Rehabil 2005;86(12 Suppl 2):S101-14.

Objective: To examine associations of patient characteristics, rehabilitation therapies, neurotropic medications, nutritional support, and timing of initiation of rehabilitation with functional outcomes and discharge destination for inpatient stroke rehabilitation patients.

Design: Prospective observational cohort study.

Setting: Five U.S. inpatient rehabilitation facilities.

Participants: Poststroke rehabilitation patients (N=830; age, >18y) with moderate or severe strokes, from the Post-Stroke Rehabilitation Outcomes Project database.

Interventions: Not applicable.

Main Outcome Measures: Discharge total, motor, and cognitive FIM scores and discharge destination.

Results: Controlling for patient differences, various activities and interventions were associated with better outcomes including earlier initiation of rehabilitation, more time spent per day in higher-level rehabilitation activities such as gait, upper-extremity control, and problem solving, use of newer psychiatric medications, and enteral feeding. Several findings part with conventional practice, such as starting gait training in the first 3 hours of physical therapy, even for low-level patients, was associated with better outcomes.

Conclusions: Specific therapy activities and interventions are associated with better outcomes. Earlier rehabilitation admission, higher-level activities early in the rehabilitation process, tube feeding, and newer medications are associated with better stroke rehabilitation outcomes.

Key Words: Cerebrovascular accident; Outcome assessment; Rehabilitation; Severity of illness; Stroke.

A MAJOR CHALLENGE in stroke rehabilitation practice is how best to customize available rehabilitation resources to meet the needs of patients to optimize outcomes.[1] Failure to optimize rehabilitation interventions and therapies can result in too little or too much care relative to a patient's needs and preferred outcomes. The association of stroke rehabilitation outcomes with process of care and patient characteristics has not been studied comprehensively. Stroke rehabilitation studies typically have been limited to a single set or subset of interventions and rarely examine all the processes of care concurrently.[2] Other studies, most of which involved limited numbers of patients, have described physical therapy (PT),[3-7] occupational therapy (OT),[8-12] and speech and language pathology (SLP)[13-16] in terms of duration or frequency but have rarely described specific activities preformed during therapy sessions.

The introductory article in this series presents the motivation, purpose, and scope of this study, as well as an extended literature review that establishes the case for the multicenter Post-Stroke Rehabilitation Outcomes Project (PSROP)[1] on which the findings presented in this article are based. Other articles in this series have documented the nature, scope, and variation of stroke rehabilitation practice as uncovered in the PSROP.[17-24]

Building on previous articles in this series that identified individual links between stroke rehabilitation patient characteristics, practices, and outcomes, this article seeks to put all of these together and describe the most significant associations between patient characteristics, PT, OT, SLP, neurotropic medications, nutritional support, and timing of initiation of rehabilitation with motor and cognitive functional outcomes and discharge destination. In short, we want to determine how specific rehabilitation therapies relate to outcomes, taking into account patient covariates.

One suggestion that emerged in previous PSROP articles is that challenging patients to perform higher-order tasks as early as possible in their rehabilitation stay, even when they may not appear ready to take on such activities, is associated with better outcomes. In other words, stroke rehabilitation patients may be able to leap-frog over lower-level activities prescribed by current traditional practice. This article further tests the hypothesis that earlier and more aggressive therapies (such as earlier rehabilitation, newer medications, enteral feeding, and higher-level therapies from physical, occupational, and speech and language therapists) are associated with better outcomes, taking into account each patient's demographic, health, and functional profile. The leap-frog hypothesis challenges conventional wisdom in rehabilitation that patients should move incrementally through the rehabilitation process and that patients should be challenged to perform activities that are only a notch above their previous level of performance in the rehabilitation process. Conventional wisdom is based, in part, on the human development axiom that one must learn to crawl before one can walk and on the notion that the patient should not be challenged excessively for fear that it may induce a sense of failure or stress, if not depression, and thus compromise outcome.

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Table 1: Patient Variables for Moderate (CMGs 104–107) and Severe (CMGs 108–114) Stroke Groups for Multiple Regression Analyses

Patient Variables	CMGs 104–107 (n=389)	CMGs 108–114 (n=441)	*P*
Demographic and health plan characteristics			
Mean age (y)	66.2	67.9	.092*
Female (%)	48.1	46.9	.781†
Race (%)			.611†
White	64.5	61.2	
Black	16.7	18.6	
Other	18.8	20.2	
Payer (%)			.102†
Medicare	57.3	63.0	
Other	42.7	37.0	
Health and functional status characteristics			
Type of stroke (%)			.068†
Hemorrhagic	22.9	28.6	
Ischemic	77.1	71.4	
Side of stroke (%)			.304†
Right	46.3	42.2	
Left	42.9	43.3	
Bilateral	9.3	11.6	
Unknown	1.5	3.0	
Location of stroke (%)			.030†
Brainstem/cerebellum	20.1	13.8	
Subcortical	30.9	39.2	
Brainstem + subcortical	6.2	4.1	
Lobar	37.3	37.4	
Unknown	5.7	5.4	
BMI/weight (%)			.115†
Underweight BMI (<18.5kg/m^2)	4.4	3.9	
Normal BMI (18.5–24.9kg/m^2)	44.5	36.7	
Overweight BMI (25–29.9kg/m^2)	33.4	37.6	
Obese BMI (≥30kg/m^2)	17.7	21.8	
Mean admission total FIM ± SD	71.6±9.9	43.1±12.6	<.001*
Mean admission motor FIM ± SD	47.8±5.7	26.6±7.2	<.001*
Mean admission cognitive FIM ± SD	23.8±7.3	16.5±7.6	<.001*
Mean admission CSI ± SD	15.8±10.4	27.3±15.2	<.001*
Stroke symptoms			
Dysphagia (%)			<.001†
Normal	54.2	21.5	
Dysphagia not otherwise specified	32.7	44.9	
Unable to swallow liquids or solids	13.1	33.6	
Motor impairment (%)			<.001†
Mild motor impairment	10.0	7.5	
Moderate motor impairment	86.1	76.0	
Severe motor impairment	3.9	16.6	
Aphasia (%)	14.9	32.9	<.001†
Neurobehavioral impairment			<.001†
Mood/behavior disturbances	38.3	33.6	
Cognitive dysfunction	4.1	8.8	
Both	8.0	16.8	
Certain neurotropic medications, no mood/behavior or cognitive dysfunction	22.9	26.5	
None	26.7	14.3	
Prerehabilitation health care			
Mean no. of days from stroke symptom onset to rehabilitation admission ± SD	11.4±12.7	18.5±29.5	<.001*

Abbreviation: SD, standard deviation.
*t test.
†Chi-square test.

The PSROP is well equipped to evaluate associations between stroke rehabilitation patients, processes, and outcomes.[17] It provides detailed, comprehensive data on stroke patient characteristics, rehabilitation treatments and interventions, and outcomes. It allows clinicians and researchers to drill down to the most meaningful level of resolution regarding the types of care rendered. Previous studies, as noted in the introductory article of this supplement, do not provide this level of resolution,[1] nor do they provide the data required to determine how various sequences of services or activities may prove more efficient and effective than

others in achieving better functional outcomes and more independent postdischarge living arrangements. This article presents promising insights that sometimes contradict conventional wisdom in stroke rehabilitation and suggest further exploration that is beyond the immediate scope of this article.

METHODS

The methodology governing the full PSROP is provided by Gassaway et al[17]; Gassaway provides a detailed description of the larger study's participating facilities, patient selection criteria, data collection instruments including their validity and reliability, and a detailed description of the project's final study group. The methodology is summarized in Maulden et al.[23] The institutional review boards at Boston University and at each participating inpatient rehabilitation facility (IRF) approved the study.

Subsets of Patients With Moderate and Severe Strokes

We examined a subset (n=1079) of the total 1161 patients in the U.S. PSROP database who had FIM scores available to categorize into case-mix groups (CMGs). Because we wanted to analyze the effects of the 3 primary rehabilitation therapies (PT, OT, SLP) and 1 site provided almost no SLP information to the PSROP database, we deleted all patients from that 1 site. To maintain sample sizes large enough to detect small effects, CMGs were combined into moderate (CMGs 104–107, 389 patients) and severe (CMGs 108–114, 441 patients) patient groups. We focused regression analyses on patients with moderate and severe strokes; there were too few patients with mild stroke to be analyzed at this time (CMGs 101–103, 62 patients).

Here we briefly define the variables found to be significant in the multivariate analyses that follow.

Patient variables (table 1) include demographic characteristics, health and functional status characteristics (type and location of stroke, body mass index [BMI], admission functional status [FIM score], admission severity of illness [Comprehensive Severity Index (CSI) and its components]), indications of neurobehavioral impairments, and prerehabilitation health care information. BMI on admission was categorized as underweight ($<18.5 kg/m^2$), normal ($18.5-24.9 kg/m^2$), overweight ($25.0-29.0 kg/m^2$), and obese ($\geq 30.0 kg/m^2$). Time from stroke symptom onset to rehabilitation admission was calculated from the number of days from first symptom onset to admission to a dedicated rehabilitation unit.

CSI, a disease-specific severity assessment system, calculates severity scores using individual components of physical findings and laboratory results at specified levels of abnormality found in a resident's chart based on diseases defined by *International Classification of Diseases, 9th Revision* (ICD-9),[25] coding. For stroke diagnosis, CSI components include degree of alertness, ataxia, aphasia, dysarthria, dyspnea, perceptual and sensation impairment, dysphagia, hemiplegia, lesion level, time postinjury, and acute confusion. The functional performance for each study patient on admission to and discharge from inpatient rehabilitation was obtained via retrospective chart review using the study site's reporting of the FIM. We assumed all clinicians providing FIM data within IRFs as part of standard practice were FIM credentialed.[17]

A patient was defined as having neurobehavioral impairments if any of the following were present: (1) the patient had diagnoses associated with neurologic or behavioral impairment(s) documented in their chart (eg, major depression, ICD-9 codes 296.2 and 296.3); (2) mood or behavioral impairments were indicated in charted descriptors such as combative, agitated, restless, aggressive, anxious, depressed, emotionally labile, having hallucinations, flat affect, or impulsive; (3) cognitive impairments were indicated in charted descriptors such as decreased safety awareness, impaired or poor judgment or concentration, impaired memory, confused, disoriented, or lethargic; and (4) patients received certain neurotropic medication(s) but had no charted descriptions of mood/behavior or cognitive impairments.[21] These neurotropic medications included antidepressants, benzodiazepines, anxiolytics, and antipsychotics. Process variables (table 2) included rehabilitation length of stay (LOS); details of PT, OT, and SLP activities derived from point-of-care intervention documentation forms; and use of specific treatments, including nutrition supplementation via tube feeding and neurotropic medications, obtained from postdischarge chart review.[17-23]

The study's physicians, nurses, psychologists, social workers, and physical, occupational, recreational, and speech therapists each completed point-of-care intervention documentation forms for each patient treatment session. We calculated the total number of minutes per patient per day spent in each therapy (PT, OT, SLP) and in each therapy activity by dividing the total (full stay) number of minutes in each therapy activity by the LOS.[18-20]

Tube-feeding data included date, type, and reason a tube was placed and start and stop times of enteral formulas.[22] Based on these data, we divided patients into 3 tube-feeding groups: (1) no tube feeding during rehabilitation (n=666), (2) tube feeding at any time during rehabilitation but discontinued before discharge (n=131), and (3) tube feeding for 100% of rehabilitation stay and discharged on tube feeding support (n=33). "Discharged on tube feeding support" was defined as (1) the patient's last ordered diet type was nothing by mouth (no oral intake) or a speech and language pathologist was supervising all oral intake, (2) the CSI discharge severity indicator of the patient's dysphagia status 24 hours before discharge indicated that the patient was unable to swallow liquids or solids, (3) a percutaneous endoscopic gastrostomy or other gastrostomy tube was in place, and (4) the patient was discharged to a skilled nursing facility (SNF) or home health. Group 3 patients—patients who received tube feeding for their entire rehabilitation stay and were discharged with tube feeding (n=33)—were excluded from regression analyses. They were sicker patients overall (higher CSI scores) but had similar motor and cognitive abilities on admission as other tube-fed patients. However, they had significantly lower abilities at the time of discharge, showing lack of progress during rehabilitation, which is supported by their short LOSs and discharge to institutional care.[22] The project team determined they were an outlier group for whom the severity of dysphasia and subsequent recovery time frame were well outside usual recovery patterns.

Neurotropic medication information was collected at the drug level (including details about dosing and timing) and then grouped into categories by consensus of prescribing physicians of the PSROP clinical team based on similarity of drug content and effects on patients. Medications contained in drug categories used in these analyses, structured around medication groupings found in ePocrates,[26] are listed elsewhere.[21]

Outcome variables (table 3) included discharge function, severity of illness, and discharge destination. Function, as measured by the FIM, was captured as recorded at discharge, and change in FIM score (total, motor, cognitive) from admission to discharge was calculated. We captured the maximum CSI score and calculated increases in severity during rehabilitation from admission CSI to maximum CSI scores, which includes the most aberrant signs and symptoms regardless of when they occur.

Table 2: Process Variables for Moderate (CMGs 104–107) and Severe (CMGs 108–114) Stroke Groups for Multiple Regression Analyses

Process Variables	CMGs 104–107 (n=389)	CMGs 108–114 (n=441)	*P*
Mean LOS	15.7±7.2	24.5±10.9	<.001*
PT (mean ± SD)			
No. of min/d	43.5±13.6	41.4±13.9	.033*
Activities (no. of min/d)			
Bed mobility	0.7±1.0	2.5±2.3	<.001*
Sitting	0.6±1.3	2.6±3.6	<.001*
Transfers	3.2±3.1	6.1±3.9	<.001*
Sit-to-stand	2.0±2.3	3.6±2.7	<.001*
Wheelchair mobility	0.5±0.9	1.5±1.4	<.001*
Pregait	3.1±3.1	3.3±3.0	.421*
Gait	16.5±7.9	10.4±7.5	<.001*
Advanced gait	2.9±3.5	1.0±1.7	<.001*
Community mobility	1.2±2.5	0.5±1.5	<.001*
OT (mean ± SD)			
No. of min/d	40.9±15.3	39.1±15.6	.080*
Activities (no. of min/d)			
Bathing	2.1±2.5	2.1±2.3	.430*
Dressing	5.5±4.7	7.1±5.3	<.001*
Grooming	1.6±1.8	2.7±2.6	<.001*
Toileting	1.2±1.7	1.5±1.9	.025*
Feeding/eating	0.8±2.7	1.4±3.4	.001*
Transfers	2.0±2.0	2.3±2.7	.044*
Bed mobility	0.1±0.4	0.4±0.8	<.001*
Functional mobility	3.5±3.8	1.6±2.0	<.001*
Home management	3.9±4.8	1.3±2.1	<.001*
Community integration	2.0±3.2	0.8±1.9	<.001*
Leisure performance	0.8±1.5	0.7±1.3	.580*
Upper-extremity control	9.3±8.4	9.3±6.6	.989*
Wheelchair management	0.3±0.7	0.5±1.1	.001*
Sitting balance/trunk control	0.6±1.2	1.5±2.1	<.001*
SLP (mean ± SD)			
No. of min/d	25.6±16.2	31.5±15.2	<.001*
Activities (no. of min/d)			
Swallowing	3.4±6.5	6.7±8.3	<.001*
Speech/intelligibility	2.1±4.2	2.3±4.0	.394*
Voice	0.4±1.5	0.8±2.2	.005*
Verbal expression	2.9±4.8	4.0±5.4	.002*
Alternative/nonverbal expression	0.3±1.3	0.6±1.8	.005*
Written expression	0.9±2.1	0.8±1.7	.408*
Auditory comprehension	1.6±2.8	3.1±4.1	<.001*
Reading comprehension	1.4±2.3	1.4±2.2	.890*
Problem solving/reasoning	3.8±5.6	3.3±4.5	.154*
Orientation	0.6±1.5	1.1±2.0	<.001*
Attention	0.9±2.2	1.7±2.9	<.001*
Memory	1.4±3.0	1.4±2.5	.743*
Pragmatics	0.1±0.5	0.1±0.5	.551*
Executive functional skills	0.7±1.5	0.4±1.2	.001*
Tube feeding use during rehabilitation (%)			<.001†
Use discontinued before discharge	5.4	24.9	
Use continued on discharge	1.3	6.4	
None	93.3	68.7	
Neurotropic medications (%)			
Old anticonvulsant	2.8	3.0	1.000†
Opioid analgesics	18.6	29.5	<.001†
Analgesic; muscle relaxant	5.4	9.5	.026†
New SSRIs	7.5	14.3	.002†
Old SSRIs	18.0	21.8	.192†
Atypical antipsychotics	4.6	12.9	<.001†
Anti-Parkinson's	6.4	12.5	.003†
Anxiolytics	1.0	3.0	.083†
Modafinil	0.5	8.6	<.001†
Neurostimulants	3.3	13.2	<.001†

Table 2 (Cont'd): Process Variables for Moderate (CMGs 104–107) and Severe (CMGs 108–114) Stroke Groups for Multiple Regression Analyses

Variables	CMGs 104–107 (n = 389)	CMGs 108–114 (n = 441)	P
Old antinausea/antivomiting	10.3	17.7	.003†
Other antidepressants	18.0	35.4	<.001*
Benzodiazepines	11.3	13.2	.459†

Abbreviation: SSRIs, selective serotonin reuptake inhibitors.
*t test.
†Chi-square test.

Analysis Methods

Descriptive statistics were used to compare patient characteristics, therapy interventions, and outcomes for patients with moderate and severe strokes (see tables 1–3). Chi-square tests were used for categoric data and *t* tests or analysis of variance for continuous data.

We used ordinary least squares (OLS) multiple regression to examine associations between "onset days" (days from symptom onset to rehabilitation admission), medications used, nutritional support, and minutes of PT, OT, and SLP activity per patient per day with each patient's functional outcome at discharge, controlling for patient characteristics, stroke symptoms, neurobehavioral impairment, and rehabilitation LOS. We used logistic regression analyses to determine associations of the same patient characteristics and treatments with the outcomes of discharge destination to home or community or achieving specified increases in FIM components.

Variables entering regression models were checked for multicollinearity; no correlations were greater than .60. Stepwise R^2 selection procedure for OLS regressions allowed independent variables to enter and leave each model. The importance of each predictor was determined by its F value (or Wald chi square in logistic regression). We created the most parsimonious model for each outcome by allowing only significant ($P<.05$) variables to remain in the model. Variables that were allowed to enter models are listed in appendix 1. All analyses were performed with SAS statistical software.[a]

Analyses were performed within moderate and severe (CMG) stroke subpopulations. For analyses involving FIM outcomes, we excluded patients who were discharged to acute care or to another rehabilitation facility (7 patients with moderate and 37 with severe stroke) because we did not have access to FIM data scored by other facilities on discharge to home or SNF. Missing continuous data resulted in exclusion of those subjects from analyses.

For both the moderate and severe stroke CMG groupings, we performed separate regression analyses that included (1) variables based on therapy activities during the entire rehabilitation stay (tables 4, 5) and (2) variables based on therapy activities during the first block of therapy only (tables 6–8). First block of therapy is defined as receiving PT, OT, and SLP for at least 3 hours each (4h for OT) and includes activity time during only the first 3-hour (4h for OT) block. Thus, sample sizes are smaller in the first block of therapy only (see tables 6–8), because some rehabilitation patients received therapy for less than the defined first block period. Reasons for defining these blocks of time are presented elsewhere.[18-20]

For first block analyses we included only time in each activity (excluding time spent in assessment) during the first block of PT, OT, and SLP treatment time, regardless of the total number of therapy blocks a patient received during the entire rehabilitation stay. This ensured that patients were functioning at the identified FIM locomotion, transfer, and communication levels (as measured by admission FIM score), among others, at the time of receiving the therapy activities. Because we did not measure incremental increases in FIM scores during the rehabilitation stay, it was important to reduce the confounding effect of naturally improving function (natural recovery) over the course of rehabilitation. Associating outcomes at discharge with time in activities throughout the whole stay might be confounded by the natural recovery process. By using the first block of therapy, we hypothesized that patients would not

Table 3: Outcome Variables for Moderate (CMGs 104–107) and Severe (CMGs 108–114) Stroke Groups for Multiple Regression Analyses

Outcome Variables	CMGs 104–107 (n = 389)	CMGs 108–114 (n = 441)	P
Severity (CSI) during rehabilitation			
Mean maximum CSI ± SD	23.0 ± 14.7	41.4 ± 23.3	<.001*
Increase in severity (maximum − admission)	7.2±8.3	14.1±13.3	<.001*
Mean discharge CSI ± SD	6.4±7.1	14.8±14.1	<.001*
FIM			
Mean discharge total FIM ± SD	97.7±12.8	72.3±21.7	<.001*
Mean increase in total FIM ± SD (discharge − admission)	26.2±10.8	29.1±16.9	.003*
Mean discharge motor FIM	69.9±10.0	50.4±16.8	<.001*
Mean increase in motor FIM ± SD (discharge − admission)	22.2±9.2	23.8±14.3	.051*
Mean discharge cognitive FIM ± SD	27.7±6.1	21.8±7.6	<.001*
Mean increase in cognitive FIM ± SD (discharge − admission)	4.0±3.6	5.2±4.5	<.001*
Discharge destination (%)			<.001†
Home/community	93.3	67.1	
SNF	4.9	24.5	
Hospital or other rehab	1.8	8.4	

*t test.
†Chi-square test.

Table 4: Full Regressions for Moderate Stroke Patients CMGs 104–107

Independent Variables	Discharge FIM (R^2=.604, n=372)*†			Discharge Motor FIM (R^2=.511, n=373)*			Discharge Cognitive FIM (R^2=.793, n=376)†		
	Coeff	F	*P*	Coeff	F	*P*	Coeff	F	*P*
Patient variables									
Age	−0.109	15.01	<.001	−0.073	9.04	.003			
Female				−1.641	5.00	.026			
BMI underweight	−4.795	4.42	.036						
Stroke location: brainstem/cerebellum				−2.382	7.03	.008			
Admission FIM motor score	0.411	24.10	<.001	0.403	31.39	<.001			
Admission FIM cognitive score	0.666	86.25	<.001				0.668	732.56	<.001
Aphasia							−1.147	6.01	.015
Moderate motor impairment				−3.000	6.96	.009			
No. of days from stroke symptom onset to rehabilitation admission	−0.135	16.68	<.001	−0.090	9.97	.002			
Process variables									
LOS	−0.153	5.65	.018	−0.231	15.59	<.001			
PT: formal assessment (min per patient per d)				−0.374	10.41	.002			
PT: bed mobility (min per patient per d)	−1.503	8.14	.005	−1.300	8.75	.003			
PT: sitting (min per patient per d)	−0.781	4.98	.026						
PT: transfers (min per patient per d)	−0.373	5.26	.022	−0.395	7.78	.006			
PT: gait (min per patient per d)				0.129	6.48	.011			
PT: advanced gait (min per patient per d)				0.247	4.86	.028			
OT: feeding/eating (min per patient per d)							−0.139	6.50	.011
OT: bathing (min per patient per d)	0.595	9.41	.002						
OT: toileting (min per patient per d)	−1.356	22.99	<.001	−0.803	12.26	.001			
OT: sitting balance (min per patient per d)	−0.971	7.76	.006						
OT: transfers (min per patient per d)				−0.426	4.67	.031			
OT: home management (min per patient per d)	0.249	7.25	.007	0.261	10.16	.002			
OT: upper-extremity control (min per patient per d)	0.189	12.16	<.001	0.130	7.32	.007			
SLP: speech/intelligibility (min per patient per d)	−0.223	5.14	.024	−0.193	5.16	.024			
SLP: voice (min per patient per d)	1.064	12.76	<.001	0.627	6.54	.011			
SLP: auditory comprehension (min per patient per d)	−0.570	11.14	<.001	−0.397	8.73	.003	−0.162	7.59	.006
SLP: reading comprehension (min per patient per d)				0.341	4.22	.041			
SLP: problem solving (min per patient per d)	0.208	7.00	.009	0.137	4.41	.037	0.054	4.18	.042
SLP: attention (min per patient per d)	0.529	6.44	.012						
SLP: executive functioning (min per patient per d)	−0.696	5.92	.016						
Medications									
Opioid analgesics	3.140	8.68	.003	2.227	5.73	.017	0.725	3.90	.049
Atypical antipsychotics	6.127	9.28	.003	4.625	7.29	.007			
New SSRIs							1.260	4.96	.027
Anti-Parkinson's	−7.641	19.65	<.001	−4.577	9.60	.002	−1.894	9.91	.002

NOTE. Blank cells refer to variables and the coefficient, F, and *P* values that did not enter the model significantly.
Abbreviation: Coeff, coefficient.
*Missing 4 discharge motor FIM scores.
†Missing 1 discharge cognitive FIM scores.

have time to improve their functioning naturally as they might have if we included all therapy blocks in regression analyses.

RESULTS

Patient, Process, and Outcomes Characteristics

Patient, process, and outcome characteristics for the 830 patients with moderate and severe stroke are presented in tables 1 through 3, respectively. Demographically, the samples are similar, although the severe stroke group is slightly older. As expected, the severe stroke group differed significantly in many other patient characteristics (see table 1). They had significantly higher admission severity scores (CSI), and individual component scores of the CSI (dysphagia, complete hemiplegia or worse, aphasia, mood and cognitive disturbances) also were more severe. By definition, the severe stroke group also had significantly lower admission FIM scores (total, motor, cognitive). In addition, the severe stroke group had more time between onset of stroke symptoms and rehabilitation admission.

Many process variables also were significantly different between the moderate and severe stroke groups (see table 2). Rehabilitation LOS was significantly longer for the severe stroke group. Time spent in therapy activities varied among the 2 groups, often significantly. Significantly more time was spent on higher-level PT (gait, advanced gait, community mobility), OT (home management and community integration), and SLP activities (executive function skills) in the moderate stroke group. Tube feeding was used significantly more with patients with severe stroke. Medications administered to the 2 groups also were different for several classes of neurotropic medications: there was greater use of opioid analgesics, analgesic

Table 5: Full Regressions for Severe Stroke Patients CMGs 108–114

	Discharge FIM (R^2=.728, n=372)*			Discharge Motor FIM (R^2=.676, n=372)*			Discharge Cognitive FIM (R^2=.796, n=376)			Discharge Home and Assisted Living (c=.836, n=413)		
Independent Variables	Coeff	F	P	Coeff	F	P	Coeff	F	P	Coeff	Wald	P
Patient variables												
Age	−0.219	25.80	<.001	−0.202	31.94	<.001						
Race: black	−3.253	4.74	.030	−2.981	5.58	.019						
Admission FIM motor score	0.430	12.96	<.001	0.378	15.48	<.001				0.075	10.39	.001
Admission FIM cognitive score	0.880	81.82	<.001	0.297	14.99	<.001	0.575	345.80	<.001			
Aphasia							−1.429	8.48	.004			
Mild motor impairment	6.041	7.24	.008	5.010	7.14	.008						
Neurobehavioral impairment: mood and cognitive disturbances (both)	−4.185	6.64	.010				−2.389	24.54	<.001			
No. of days from stroke symptom onset to rehabilitation admission	−0.085	18.01	<.001	−0.080	22.81	<.001						
Process variables												
LOS	0.180	7.38	.007				0.091	30.42	<.001	0.037	7.29	.007
PT: formal assessment (min per patient per d)	−0.880	8.97	.003	−0.948	17.01	<.001				−0.210	7.41	.007
PT: bed mobility (min per patient per d)	−1.547	22.80	<.001	−1.469	33.71	<.001						
PT: transfers (min per patient per d)										0.167	16.42	<.001
PT: gait (min per patient per d)	0.527	31.19	<.001	0.497	39.60	<.001				0.065	8.12	.004
PT: advanced gait (min per patient per d)	2.010	29.02	<.001	1.845	35.87	<.001	0.427	16.8	<.001	0.364	9.57	.002
OT: dressing (min per patient per d)										−0.094	11.39	<.001
OT: grooming (min per patient per d)	−0.701	6.37	.012				−0.225	8.09	.005			
OT: bed mobility (min per patient per d)							−0.567	4.85	.028			
OT: functional mobility (min per patient per d)							0.234	7.17	.008			
OT: community integration (min per patient per d)							0.310	11.73	<.001			
OT: home management (min per patient per d)	1.189	17.30	<.001	0.998	17.20	<.001				0.372	10.77	.001
OT: wheelchair (min per patient per d)										−0.361	8.05	.005
SLP: swallowing (min per patient per d)				−0.179	6.76	.010						
SLP: verbal expression (min per patient per d)							0.129	7.79	.006			
SLP: auditory comprehension (min per patient per d)							−0.282	19.99	<.001			
SLP: reading comprehension (min per patient per d)				0.470	4.59	.033						
SLP: problem solving (min per patient per d)	0.437	10.76	.001				0.192	22.06	<.001			
SLP: orientation (min per patient per d)	−0.985	9.03	.003	−0.692	6.49	.011	−0.457	21.69	<.001			
SLP: attention (min per patient per d)										−0.102	5.60	.018
Tube feeding during rehabilitation	3.651	5.60	.019	4.172	9.80	.002						
Medications												
Old SSRIs	−3.867	7.50	.007	−3.447	8.35	.004						
Modafinil	−10.70	16.77	<.001	−8.730	16.32	<.001						
Anti-Parkinson's	−6.388	12.40	<.001	−4.908	10.44	.001						

NOTE. Blank cells refer to variables and their coefficient, F, and *P* values that did not enter the model significantly.
*Missing 4 discharge motor FIM scores.

Table 6: Full Regressions for Moderate Stroke Patients CMGs 104–107, First Therapy Block Only

Independent Variables	Discharge FIM (R^2=.546, n=283)*			Discharge Motor FIM (R^2=.480, n=283)*			Discharge Cognitive FIM (R^2=.772, n=287)		
	Coeff	F	P	Coeff	F	P	Coeff	F	P
Patient variables									
Age	−0.154	19.81	<.001	−0.143	23.95	<.001	−0.024	4.69	.031
Stroke location: brainstem/cerebellum				−2.943	7.73	.006			
Stroke location: subcortical	2.318	4.40	.037						
Admission FIM motor score	0.481	23.95	<.001	0.457	30.55	<.001			
Admission FIM cognitive score	0.613	52.83	<.001				0.688	619.09	<.001
Aphasia							−1.181	5.52	.020
Moderate motor impairment	−4.853	9.69	.002	−5.598	18.09	<.001			
No. of days from stroke symptom onset to rehabilitation admission	−0.094	6.09	.014	−0.078	5.72	.018			
Process variables									
LOS	−0.205	7.57	.006	−0.189	8.74	.003			
PT: sitting (min in first 3h of therapy)				−0.161	5.34	.022			
PT: transfers (min in first 3h of therapy)				−0.095	8.30	.004			
PT: gait (min in first 3h of therapy)	0.059	10.23	.002	0.046	8.15	.005			
OT: bathing (min in first 4h of therapy)				−0.060	5.27	.022			
OT: feeding/eating (min in first 4h of therapy)	−0.060	6.10	.014	−0.050	6.12	.014			
OT: toileting (min in first 4h of therapy)							0.038	5.75	.017
SLP: voice (min in first 3h of therapy)	0.093	4.79	.030	0.115	10.16	.002			
SLP: auditory comprehension (min in first 3h of therapy)	−0.162	19.64	<.001	−0.091	9.60	.002	−0.028	5.27	.023
Medications									
Old anticonvulsants	6.655	4.67	.032	5.173	3.87	.050			
Analgesics; muscle relaxant	−7.560	11.39	<.001	−7.446	15.00	<.001			
Opioid analgesics	2.972	5.27	.022	2.388	4.65	.032			
Neurostimulants	−7.076	6.32	.013						
Anti-Parkinson's	−4.962	5.61	.019				−2.320	11.17	.001
Old antinausea/antivomiting							1.180	3.97	.047

NOTE. Blank cells refer to variables and their coefficient, F, and *P* values that did not enter the model significantly.
*Missing 4 discharge motor FIM scores.

muscle relaxants, new selective serotonin reuptake inhibitors (SSRIs), atypical antipsychotics, anti-Parkinson's medications, modafinil, neurostimulants, other antidepressants, and old antinausea and antivomiting medications in patients with severe stroke.

Outcome measures also varied significantly for patients with moderate and severe stroke. Discharge total, motor, and cognitive FIM scores were higher for patients with moderate stroke. However, patients with severe stroke achieved greater increases in total, motor, and cognitive FIM scores from admission to discharge. Discharge and maximum CSI scores were significantly higher (indicating sicker patients) for patients with severe stroke; patients with severe stroke also had a greater increase in severity during rehabilitation. Significantly more patients with moderate stroke were discharged to home or community (see table 3).

Regression Results for All Patients With Moderate and Severe Stroke

We allowed many variables (eg, demographics; function at admission [FIM score]; medical severity of illness [maximum CSI score]; components of severity; stroke location; minutes per day spent on PT, OT, and SLP activities; medication class; nutritional support; LOS) (see tables 1, 2) to enter stepwise selection regression models to identify those variables associated with higher or lower functional outcome by discharge or more or less likelihood of being discharged to home or community versus institution (SNF, hospital, other rehabilitation center).

Tables 4 and 6 present 2 regression approaches for patients with moderate CMG (104−107) stroke, and tables 5 and 7 present 2 regression approaches for patients with severe CMG (108−114) stroke. The first approach for each group contained information and interventions from the full rehabilitation stay (see table 4); the second approach (see table 6) used the amount of PT, OT, and SLP from the first block of therapy only. Outcomes included discharge total, motor, and cognitive FIM scores. In addition, for the severe stroke group (CMG 108−114) we included discharge destination as a fourth outcome. Discharge destination was not used as an outcome for patients with moderate stroke because almost all of these patients went home (see table 3).

Demographic Variables

In each model, older patients were associated with lower discharge FIM scores for at least 2 specified outcomes. Race (ie, black) was associated with lower discharge total and motor FIM scores for patients with severe stroke.

Health and Functional Status Variables

Stroke location. Patients in the moderate group with brainstem and cerebellar strokes were associated with lower discharge motor FIM scores.

Table 7: Full Regressions for Severe Stroke Patients CMGs 108–114, First Therapy Block Only

	Discharge FIM (R^2 .559, n=331)*			Discharge Motor FIM (R^2 .479, n 331)*			Discharge Cognitive FIM (R^2=.742, n=335)			Discharge Home and Assisted Living (c .745, n 365)		
Independent Variables	Coeff	F	P	Coeff	F	P	Coeff	F	P	Coeff	Wald	P
Patient variables												
Age	−0.330	30.98	<.001	−0.324	43.14	<.001						
Race: other							−1.153	5.33	.022			
Stroke side: right brain							1.289	9.39	.002			
Admission FIM motor score	0.635	17.78	<.001	0.656	27.53	<.001				0.113	31.66	<.001
Admission FIM cognitive score	0.959	63.71	<.001	0.216	4.65	.032	0.666	362.28	<.001			
Maximum severity score (CSI)	−0.081	3.92	.048				−0.031	8.83	.003			
Aphasia							−1.063	4.23	.041			
Severe motor impairment	−7.871	11.53	<.001	−6.094	9.73	.002	−1.482	6.08	.014			
No dysphagia				3.405	4.53	.034						
Neurobehavioral impairment: mood and cognitive disturbances (both)	−4.846	5.20	.023				−1.964	11.11	.001	−0.671	4.12	.042
Neurobehavioral impairment: neurotropic medications, no mood/ behavior or cognitive dysfunction				3.364	5.04	.026						
No. of days from stroke symptom onset to rehabilitation admission	−0.119	21.47	<.001	−0.114	27.62	<.001	−0.014	4.07	.045			
Process variables												
LOS	0.395	22.26	<.001	0.246	12.78	<.001	0.127	36.58	<.001	0.068	25.50	<.001
PT: bed mobility (min in first 3h of therapy)	−0.170	6.54	.011	−0.168	9.03	.003						
PT: gait (min in first 3h of therapy)	0.121	13.06	<.001	0.106	13.95	<.001						
PT: advanced gait (min in first 3h of therapy)	0.337	4.81	.029	0.268	4.27	.040	0.126	9.01	.003			
OT: bed mobility (min in first 4h of therapy)							−0.070	4.37	.037			
OT: home management (min in first 4h of therapy)	0.176	6.57	.011	0.159	7.48	.007						
SLP: problem solving (min in first 3h of therapy)							0.023	5.16	.024			
SLP: orientation (min in first 3h of therapy)							−0.041	4.87	.028			
Tube feeding during rehabilitation	4.850	6.19	.013	4.700	7.93	.005						
Medications												
Old SSRIs	−5.346	8.27	.004	−4.616	8.73	.003						
Other antidepressant	−3.663	4.95	.027	−4.206	9.03	.003				−0.593	5.22	.022

NOTE. Blank cells refer to variables and their coefficient, F, and *P* values that did not enter the model significantly.
*Missing 4 discharge motor FIM scores.

Admission FIM score. Patients with higher admission motor and cognitive FIM scores were associated with higher discharge FIM scores and with more likelihood of being discharged home.

Severity of illness. Maximum severity scores were associated with lower discharge total and cognitive FIM scores in the first block analyses of patients with severe stroke. The high correlation of maximum severity score and admission FIM score in patients with severe stroke ($r = -.491$, $P<.001$) partially explains the CSI's overall lack of significance in regression models that include the entire rehabilitation stay. However, components of the CSI including aphasia, levels of motor impairment, neurobehavioral impairment, and dysphagia entered each model as indicated. Patients with an aphasia diagnosis were associated with lower discharge cognitive FIM scores during rehabilitation (all models).

When the CSI and its related components were not allowed to enter models by not including them in the variable selection list, the R^2 and c statistics changed little (between 0% and 4.3%). Also, none or very few other predictors changed. Hence, the models were stable. This indicates that it is important to control for the CSI and its components but that other detailed process predictor variables correlate sufficiently with the CSI to retain the overall explanatory power of the models. When detailed process data were not available, the CSI explained between 12% and 20% of additional variation in outcomes beyond patient demographic data.[17]

Time of onset of symptoms to rehabilitation admission. In all models, more time from onset of stroke symptoms to rehabilitation admission was associated with lower discharge total and motor FIM scores.

Process Variables

Length of stay. Longer rehabilitation LOS was associated significantly with lower discharge total and motor FIM scores for patients with moderate stroke. In contrast, however, for patients with severe stroke, longer LOS as associated signifi-

Table 8: Significant Therapy Variables Predicting Discharge FIM Walk and Toilet Transfer Levels, First Therapy Block Only

Independent Variables	3 to 18 Hours of PT			3 to 24 Hours of PT*			3 to 77 Hours of PT†		
	Coeff	Wald	*P*	Coeff	Wald	*P*	Coeff	Wald	*P*
Walking patients starting at admission FIM locomotion/walk level 1 and ending at level 4 or higher	n=119, *c*=.864			n=151, *c*=.836			n=177, *c*=.786		
PT: gait (min in first 3h of therapy)	0.047	15.29	<.001	0.042	16.52	<.001	0.040	18.77	<.001
PT: transfers (min in first 3h of therapy)	−0.061	9.51	.002	−0.027	3.76	.052			
PT: community mobility (min in first 3h of therapy)	−0.255	5.63	.018	−0.232	5.02	.025			
OT: home management (min in first 4h of therapy)	0.072	4.81	.028						
Admission FIM motor score							0.079	7.52	.006
Dysphagia not otherwise specified				−0.914	4.96	.026			
Neurobehavioral impairment: cognitive disturbances	2.481	6.25	.012						
Neurobehavioral impairment: mood disturbances				−1.051	6.09	.014			
LOS	0.093	6.04	.014	0.084	9.10	.003	0.066	11.46	<.001
No. of days from stroke symptom onset to rehabilitation admission							−0.017	4.34	.037
Patients starting at admission FIM toilet transfer level 1 and ending at level 4 or higher	n=113, *c*=.863			n=136, *c*=.857			n=163, *c*=.837		
PT: gait (min in first 3h of therapy)	0.033	8.63	.003	0.037	11.72	<.001	0.039	13.34	<.001
OT: feeding/eating (min in first 4h of therapy)	−0.042	5.63	.018	−0.035	5.60	.018	−0.034	6.08	.014
SLP: reading comprehension (min in first 3h of therapy)	0.078	5.70	.017	0.064	5.11	.024	0.078	8.38	.004
Admission FIM motor score	0.126	8.44	.004	0.091	4.73	.030	0.113	9.87	.002
Maximum severity score (CSI)				−0.026	4.34	.037			
LOS				0.071	5.83	.016	0.037	4.76	.029
Sedating antihistamine medication	−2.760	4.27	.039						
New antinausea/antivomiting medication							−1.641	5.07	.024

NOTE. Patients in severe stroke CMGs 108–114. Blank cells are not significant.
*Includes first (3–18h) column.
†Includes first 2 (3–18h and 3–24h) columns.

cantly with higher discharge total and cognitive FIM scores and greater likelihood of being discharged to home.

Therapy. A variety of PT, OT, and SLP activities were associated significantly with higher or lower discharge FIM scores and discharge destination. Consistently, more minutes per day spent in PT gait activities, OT upper-extremity control and home management activities, and SLP problem-solving activities were associated significantly with higher discharge FIM scores and greater rates of discharge to home. Other therapy activities were associated consistently with lower discharge FIM scores: more minutes per day spent in PT bed mobility and sitting, OT bed mobility, and SLP auditory comprehension and orientation.

Medications. Use of anti-Parkinson medications (bromocriptine, pergolide, pramipexole, carbidopa/levodopa, amantadine) was associated significantly with lower discharge FIM scores. Interestingly, only 5 (0.6%) patients had a diagnosis of Parkinson's disease. Use of new SSRI medications (citalopram, escitalopram), opioid analgesics (codeine, fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, propoxyphene), and atypical antipsychotics (clozapine, olanzapine, quetiapine, risperidone) were associated with higher discharge FIM scores; however, use of older SSRI medications (fluoxetine, paroxetine, sertraline) had a significant association with lower discharge FIM scores.

Tube feeding. Enteral tube feeding was associated significantly with higher discharge total and motor FIM scores for patients with severe stroke, even when controlling for degree of dysphagia and other variables. It was not a significant variable in regression models for patients with moderate stroke.

Regression Results for Patients Admitted at FIM Locomotion Level 1 or Toilet Transfer Level 1

It could be argued that, in tables 4 through 7, discharge FIM scores do not isolate adequately the effects of individual therapies to specific areas of function because we look at the impact of individual therapy activities on broad categories of function such as total FIM and motor FIM scores. In table 8, we take a more focused approach. We looked at patients in the severe stroke group who started at FIM locomotion/walk level 1 (n=177) and tried to determine which therapies in the early stages (first block only) made a difference in getting patients from locomotion/walk level 1 to a locomotion/walk level of 4 or higher. We also wanted to consider how important the first block of therapy was regardless of how many additional blocks of therapy a patient received in total. Here, we found that minutes of gait training in the first block of therapy was consistently the most important PT activity associated with better outcome, regardless of the total amount of PT rendered over the course of the rehabilitation stay, while controlling for other patient characteristics.

We also wanted to determine whether benefits of gait training generalized to other lower-level functional areas that one might focus on before gait training. In this case, we arbitrarily chose toilet transfer and considered those patients who started at toilet transfer level 1 and progressed to level 4 or higher (see table 8). Again, we found that amount of time spent on gait in the first block was the most important predictor in advancing from FIM toilet transfer level 1 to level 4 or higher, while controlling for

other patient covariates. Early gait training appears to allow the patient to leap-frog over lower levels of toilet transfer.

DISCUSSION

Many of the results in tables 4 through 8 are in the expected direction and are consistent with findings in other studies that have examined the relation between patient characteristics, functional status, LOS, and outcome. What is different here is the ability to examine how specific therapy activities, medications, and other interventions are associated with outcomes. There are 2 consistent findings across all regressions presented in this article. The first is that earlier is associated with better. We found a strong and consistent negative association between time of stroke symptom onset to rehabilitation admission and functional outcomes. In other words, the sooner a patient with stroke starts inpatient rehabilitation after his/her stroke, no matter how severe, the better the outcome. Moreover, we find that earlier gait activities, particularly in the first block of PT, have a significant association with outcome, regardless of how much additional therapy a patient receives or what his/her admission functioning level (FIM score) is. This second finding supports more aggressive therapy. That is, earlier participation in higher-order, more challenging therapy activities, even at the outset in the first block of therapy and even for low-functioning patients, is associated with better outcomes in general, and extended participation in lower-level activities often is associated with worse outcomes. Participation in higher-order or more difficult therapeutic activities appears to assist in the improvement of lower-level functional activities, even without direct attention to that activity. This last observation was most evident in examining how gait training during the first block of therapy was associated strongly with greater independence in toilet transfers (see table 8). Also, Hatfield et al[20] found that it may not be necessary to spend much time enhancing basic verbal expression skills. Instead, therapists should initiate problem-solving activities, and the verbal expression will come back in the process.

These findings challenge conventional wisdom in rehabilitation practice. It is important to understand the nature of this conventional wisdom and how it arises. Rehabilitation clinicians work with patients in particular ways based on how they were taught or based on therapeutic theories and approaches espoused by textbook authors. Although often unsupported by scientific evidence, the theories and approaches make a good deal of intuitive sense and become incorporated into conventional wisdom and practice.

A few examples may be helpful here. Consider Rood's clinical maxim: "Proximal stability before distal mobility." It suggests that a patient cannot learn to use their hands or feet if their trunk and proximal limbs are weak. Consider a clinical rule of thumb in rehabilitation: activities should be planned to allow a patient to be successful for 80% of trials, thus minimizing his/her frustration and risk of depression due to excessive experience of failure. Also consider the theory underlying neurodevelopmental treatment, developed from the pioneering pediatric rehabilitation work of Bobath. It is a therapeutic approach that can be described simplistically based on the observation that a child first learns to crawl and integrate spinal and brainstem reflexes before learning to walk. Finally, consider the theory underlying the Fugl-Meyer Assessment of motor recovery after stroke. It was developed as the first quantitative evaluative instrument for measuring sensorimotor stroke recovery, based on Twitchell and Brunnstrom's observations and conceptualization of the "sequential stages of motor return" in hemiplegic patients with stroke.[27] Collectively, these theories and approaches advocate starting at a patient's current level of functioning and then building gradually toward recovery of normal function. Some of our findings challenge these time-honored theories and approaches.

Other findings actually reinforce conventional wisdom. The finding that earlier is better supports the rehabilitation axiom that patients should start rehabilitation sooner rather than later and that delaying rehabilitation can have a deleterious effect on outcomes. Rehabilitation clinicians have long been concerned that, with extended stays in acute care, patients becomes progressively deconditioned and less able to partake fully in rehabilitation on transfer to a rehabilitation unit. Again, data analyses presented here suggest that the sooner patients with stroke, especially those with severe stroke, get to the rehabilitation setting, the more likely they are to have an optimal gain in FIM score and have the best chance of being discharged to home instead of being institutionalized. This may mean transferring patients who are not yet 100% stable (eg, may have a urinary tract infection or pneumonia) to a rehabilitation unit more quickly, rather than spending a few more days in the hospital waiting for complete stabilization.

Rehabilitation providers often wonder if the acute care hospital payment system encourages acute care providers to discharge patients to rehabilitation when they are not yet medically stable. The findings here suggest that "sicker and quicker" may in some cases be better. This inference is supported by the variables that have significant association with discharge total and motor FIM scores (see tables 4 through 7). A longer time between onset of stroke symptoms and admission to inpatient rehabilitation was associated with reduced discharge FIM score, after controlling for overall severity of illness or its components. This suggests that earlier admission to rehabilitation, even if a patient's severity of illness is increased according to a higher CSI score or its components, is associated with better outcomes. In any event, the findings should encourage more timely coordination in the handoff from acute care to rehabilitation for patients with stroke and more willingness of rehabilitation facilities to admit medically challenging, sicker, patients.

Once in rehabilitation, patients appear to have different responses to LOS. For patients in the moderate stroke CMGs (104–107), our findings indicate that there is a negative association of longer LOS with outcomes. However, for patients in the severe CMGs (108–114), our findings indicate that there is a strong positive association of longer LOS with outcomes. At the risk of overinterpreting these findings, one could conclude that patients with moderate stroke do better with shorter and more intense rehabilitation stays, whereas patients with severe stroke do better with a more extended rehabilitation process. More data analyses are needed to determine accurately the relation between rehabilitation LOS and outcomes among various subgroups of rehabilitation patients to identify more clearly the rehabilitation patients who would benefit from shorter or longer rehabilitation stays.

Common clinical practice also has a powerful sway in the choice of medications. A few years ago, stroke rehabilitation physicians were happy to adopt the use of SSRI medications for patients with depressed mood because of remarkably low side effect profiles compared with tricyclic antidepressants, which were notorious for side effects. The first generation of SSRIs included fluoxetine, sertraline, and paroxetine. A newer generation of SSRIs, including citalopram and escitalopram, has been developed and adopted into use by psychiatric physicians; however, rehabilitation physicians have been slower to adopt them. Given that there are few side effects from the first generation SSRIs and little to no research on the merits or side effects of newer SSRIs on patients undergoing stroke rehabil-

itation, there is no strong reason to shift to the unknown from the well established. However, our analyses indicate that stroke rehabilitation patients might benefit from such a shift.

It is also common clinical practice to avoid the use of antipsychotic medications, based on beliefs extrapolated from animal research and psychiatric literature that the antidopaminergic and anticholinergic effects of chlorpromazine and haloperidol, among others, could reduce alertness and learning capacity in stroke survivors. A new family of medications referred to as atypical antipsychotic medications (olanzepine, quetiapine, risperidone, ziprasidone) has seen little use in stroke rehabilitation because its newness, a long-standing bias against antipsychotic medications as a group, and the lack of randomized studies in the stroke population. This persists despite the growing literature showing nootropic effects of this family of medications.[21] Our analyses indicate that patients with stroke might benefit from greater use of atypical antipsychotics. Conroy et al[21] found that new atypical antipsychotic medications and second generation SSRIs appear to have a positive association with stroke rehabilitation outcomes.

Another family of medications for which there exists a long-standing bias against use in stroke rehabilitation is narcotic pain medications. Narcotics are understood to sedate patients, dull cognition, cause depression, and reduce respiratory drive and, therefore, are expected to diminish outcomes if used in stroke rehabilitation. A lack of specific research examining medication use in stroke rehabilitation allows common clinical practice to prevail. Our data suggest otherwise—that narcotic pain medications are effective in reducing pain and that patients make greater improvements in motor FIM scores with them than without, despite their sedating and cognitive dulling effects.[21]

In summary, the PSROP database is large enough that we can locate narrow subpopulations where actual clinical activities and interventions went against common clinical practice: patients given narcotic or atypical antipsychotic medications consistently, low-functioning patients (admission FIM scores of 1 for locomotion or toilet transfer) who participated in PT sessions in their first 3 hours of PT where they practiced gait activities, and patients requiring total assistance for toileting who participated in PT where a therapist practiced gait in the first 3 hours of therapy. Results from these analyses indicate a strong and consistent association of rehabilitation activities that challenge patients and stress them well beyond their current level with better outcomes; that is, they move quickly to practicing upper-extremity functional activities rather than focusing on trunk strengthening. (The trunk will strengthen secondarily out of necessity.) There seem to be positive benefits for patients to jump ahead in the established sequence of activities and leap-frog into activities that might seem excessively challenging for them according to common clinical practice.

These findings challenge rehabilitation providers to rethink how they approach patients. They suggest that many current strategies about how to help a patient improve may not be optimal. Work carried out in the PSROP is not intended to reduce the value of rehabilitation but to discover its best aspects. Rehabilitation clinicians will continue to work on trunk stability, make sure a patient can move in bed, and choose to use fluoxetine at times. The difference may be in the timing and knowing when is the best opportunity to use each technique with specific types of patients.

The findings presented here are based on findings from facilities in the United States. The larger study also included a rehabilitation facility in New Zealand. Overall, the findings here are consistent with findings arising from our comparison of practice and outcomes between facilities in the United States and New Zealand, presented in this supplement by McNaughton et al.[28] This comparison notes that U.S. stroke rehabilitation patients received earlier and more intense rehabilitation and had better outcomes despite presenting a more severe clinical profile on admission.

Limitations

Several of the PSROP's limitations are noted in the study's baseline methods article by Gassaway et al[17] and in other articles in this supplement.[18-23] Observational studies such as this, however, naturally raise several concerns. We want to address 3 of them: (1) controlling for patient differences, (2) selection bias, and (3) association versus causation. The first 2 are closely related.

The strength of an observational study depends on the study's ability to control for patient differences that would otherwise be addressed through randomization. In the absence of randomization, it is critical that important patient covariates be addressed adequately. As noted in the study's baseline methods article,[17] the study's use of the admission FIM and the CSI scores provides a comprehensive patient functional and severity profile, although there is always the chance that some unknown critical variable may have been overlooked.

Selection bias is a concern when patients are not randomly assigned to certain treatment arms or when some patients fail to enroll in the study or drop out. In this study, there was no treatment arm, sham treatment, or placebo; the study examined only existing practice. Moreover, in this study, patients entered the study consecutively as they were admitted to the facility. There was no formal enrollment or informed consent because no new intervention was being introduced—and thus there were no dropouts that might otherwise bias the study sample.

The chief criticism of any observational study of this genre is that association is not causation. We agree. But when associations remain consistent regardless of how the study group is partitioned or when the findings are tested from other vantage points, the evidence becomes increasingly persuasive and needs to be taken seriously despite the exploratory nature of the study. One of the next steps is to determine the predictive validity of the study's findings. One way this can be done is to implement the findings as suggested here and then evaluate whether the outcomes observed are those that were predicted. The field also could conduct 1 or more randomized clinical trials to test these findings to determine more conclusively the predictive validity of the findings. A more formal trial of the study's leap-frog hypothesis would be particularly compelling.

The analyses presented here examine the relation between rehabilitation activities and interventions and outcomes on discharge from rehabilitation. These findings would be even more compelling if they were also found to be true for longer-term outcomes (eg, 6 and 12mo postonset). Funding limitations simply did not allow the research team to look beyond the patients' discharge statuses.

CONCLUSIONS

The PSROP's database allows researchers and clinicians to examine a rich array of associations between rehabilitation patients, processes, and outcomes. The database enables investigators to discover treatment practices that are associated with better outcomes for patients with stroke, taking into account their demographic and clinical profiles. A key finding is that earlier and more aggressive therapy is better. We find that starting therapy sooner after a stroke and starting higher-order or more challenging activities sooner are associated with better outcomes, even with lower-level functioning patients. We find this to be the case for each of 3 rehabilitation sentinel thera-

pies—PT (early gait activities), OT (early community mobility activities), and SLP (early problem solving activities). In the area of medication use, the analyses suggest that making the jump to newer SSRI antidepressant and atypical antipsychotic medications is associated with greater ability to benefit from inpatient rehabilitation for our patients.

These findings have significant implications for future research. Our findings suggest that health care providers need to shorten the duration from onset of stroke to onset of rehabilitation and to move patients as quickly as possible to higher-level, more difficult therapy activities and that rehabilitation providers may be able to shorten the LOS for some patients but increase the LOS for others. Validation studies may lead to changes in clinical practice and health policy as it relates to rehabilitation. These findings suggest continued study to reconsider target LOSs and payment weights associated with various CMGs in the IRF prospective payment system. They provide us the opportunity to develop more creative stroke rehabilitation "products" that could better coordinate each patient's care from stroke onset to rehabilitation and to discharge.

A strength of the clinical practice improvement (CPI) approach is the ability to uncover best practices more quickly than conventional studies. Such practices can later be vetted in validation studies or through controlled trials. A dilemma we have now is determining what therapeutic activities and interventions are truly ready for prime-time controlled studies. By focusing exclusively on randomized studies, we risk wasting valuable rehabilitation research resources on studies that may show no or minimal differences. Through use of CPI studies, therapeutic activities and interventions can be identified and unproductive activities and interventions can be weeded out before such confirmatory studies. The results here require us to validate the findings (predictive validity) through actual implementation and perhaps clinical trials and to rethink aspects of stroke rehabilitation practice and policy.

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APPENDIX 1: VARIABLES ALLOWED TO ENTER AND LEAVE REGRESSION MODELS

Independent variables allowed:

- Age
- Female
- Race – black
- Race – other
- Payer – Medicare
- BMI – underweight
- BMI – normal
- BMI – overweight or obese
- Stroke type – hemorrhagic

APPENDIX 1: VARIABLES ALLOWED TO ENTER AND LEAVE REGRESSION MODELS (cont'd)

Independent variables allowed:

- Brain side – right
- Brain side – left
- Brain side – bilateral
- Stroke location – lobar
- Stroke location – subcortical
- Stroke location – brainstem/cerebellum
- Stroke location – brainstem + subcortical
- FIM score – admission motor
- FIM score – admission cognitive
- CSI severity score – maximum
- Aphasia during rehabilitation
- Level of motor impairment – severe
- Level of motor impairment – moderate
- Level of motor impairment – minimal
- Dysphagia – unable to swallow solids or liquids
- Dysphagia not otherwise specified
- Dysphagia – none or missing
- Neurobehavioral impairment – both mood/behavior disturbances + cognitive dysfunction
- Neurobehavioral impairment – cognitive dysfunction
- Neurobehavioral impairment – mood/behavior disturbances
- Neurobehavioral impairment – neurotropic medication use, no mood/behavior or cognitive dysfunction
- Number of days from stroke onset symptoms to rehabilitation
- Rehabilitation length of stay
- PT activity formal assessment, mean number of min/d
- PT activity bed mobility, mean number of min/d
- PT activity sitting, mean number of min/d
- PT activity transfer, mean number of min/d
- PT activity sit-to-stand, mean number of min/d
- PT activity wheelchair mobility, mean number of min/d
- PT activity pregait, mean number of min/d
- PT activity gait, mean number of min/d
- PT activity advanced gait, mean number of min/d
- PT activity community mobility, mean number of min/d
- OT activity formal assessment, mean number of min/d
- OT activity bathing, mean number of min/d
- OT activity dressing, mean number of min/d
- OT activity grooming, mean number of min/d
- OT activity toileting, mean number of min/d
- OT activity feeding/eating, mean number of min/d
- OT activity transfers, mean number of min/d
- OT activity bed mobility, mean number of min/d
- OT activity functional mobility, mean number of min/d
- OT activity home management, mean number of min/d
- OT activity community integration, mean number of min/d
- OT activity leisure performance, mean number of min/d
- OT activity upper-extremity control, mean number of min/d
- OT activity wheelchair mobility, mean number of min/d
- OT activity sitting balance, mean number of min/d
- SLP activity formal assessment, mean number of min/d
- SLP activity swallowing, mean number of min/d
- SLP activity speech/intelligibility, mean number of min/d
- SLP activity voice, mean number of min/d
- SLP activity verbal expression, mean number of min/d
- SLP activity alternative/nonverbal expression, mean number of min/d
- SLP activity writing expression, mean number of min/d
- SLP activity auditory comprehension, mean number of min/d
- SLP activity reading comprehension, mean number of min/d

APPENDIX 1: VARIABLES ALLOWED TO ENTER AND LEAVE REGRESSION MODELS (cont'd)

Independent variables allowed:
SLP activity problem solving, mean number of min/d
SLP activity orientation, mean number of min/d
SLP activity attention, mean number of min/d
SLP activity memory, mean number of min/d
SLP activity pragmatics, mean number of min/d
SLP activity executive functioning, mean number of min/d
Enteral tube feeding during rehabilitation
Anticonvulsant medication, new
Anticonvulsant medication, old
Anticonvulsants medication, detrimental to cognition
Antidepressant medication, other
Antidepressant medication SSRI, new
Antidepressant medication SSRI, old
Antidepressant tricyclic medication
Analgesic; muscle relaxant medication
Opioid analgesic medication
Sedating antihistamine medication
Benzodiazepine medication
Antinausea/antivomiting medication, old
Antinausea/antivomiting medication, new
Atypical antipsychotic medication
Traditional antipsychotic medication
Modafinil medication
Neurostimulant medication
Anti-Parkinson's medication
Anxiolytic medication
Hypnotic medication

Reference categories (variables not allowed in regression models):
Brain side – unknown
Stroke location – unknown
Race – white
Neurobehavioral impairment – no mood/behavior or cognitive dysfunction or neurotropic medication use

Abbreviation: SSRIs, selective serotonin reuptake inhibitors.

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ORIGINAL ARTICLE

A Comparison of Stroke Rehabilitation Practice and Outcomes Between New Zealand and United States Facilities

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ABSTRACT. McNaughton H, DeJong G, Smout RJ, Melvin JL, Brandstater M. A comparison of stroke rehabilitation practice and outcomes between New Zealand and United States facilities. Arch Phys Med Rehabil 2005;86(12 Suppl 2): S115-20.

Objective: To compare stroke rehabilitation practice and outcomes between New Zealand (NZ) and the United States.

Design: Prospective observational cohort study.

Setting: Seven inpatient rehabilitation facilities (IRFs) in the United States and NZ.

Participants: Consecutive convenience sample of 1161 patients in 6 U.S. IRFs and 130 in 1 NZ IRF (age, >18y) after acute stroke.

Interventions: Not applicable.

Main Outcome Measures: Change in FIM score and discharge destination.

Results: NZ participants were older than U.S. participants (mean: 74.1y vs 66.0y, respectively; $P<.001$). Measures of initial stroke severity were higher for U.S. participants. Mean rehabilitation length of stay (LOS) was shorter for U.S. participants (18.6d vs 30.0d, $P<.001$), but physical and occupational therapy time per patient was considerably higher despite the shorter LOS. U.S. therapists were involved in more active therapies for more of the time. Outcomes were better for U.S. participants, with fewer discharged to institutional care (13.2% vs 21.5%, $P=.006$) and larger changes in FIM scores.

Conclusions: U.S. participants with acute stroke who were selected for rehabilitation had better outcomes than NZ participants, despite shorter stays in the rehabilitation facility. U.S. participants had more intensive input from physiotherapists and occupational therapists, which may explain some of the larger increases in FIM scores. This suggests that further studies with tighter controls on case mix may add additional information on the effects of therapy intensity on patients with stroke.

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Key Words: Cerebrovascular accident; Health care systems; Outcome assessment (health care); Rehabilitation.

STROKE REHABILITATION is a complicated undertaking. Convincing evidence exists for the use of specialized stroke rehabilitation,[1] but little evidence currently exists to help stroke rehabilitation clinicians determine exactly how the details of stroke rehabilitation should be practiced. As a result, it is inevitable that different stroke rehabilitation teams will operate in different ways. These differences might be especially noticeable across different health systems, because stroke rehabilitation services react to various incentives and disincentives in an effort to provide the best care they can within resource constraints for the patients whom they manage. A comparison of the structures, processes, and outcomes of stroke rehabilitation services across different health systems might tell us much about what is important in stroke rehabilitation and give clinicians and funders in those systems information to guide future change.

Few attempts at international comparisons of stroke management have been published. The most ambitious project comparing stroke outcomes across international borders has been with the BIOMED studies in Europe.[2] These researchers attempted to relate marked differences in stroke mortality and dependency to differences in stroke practices across countries, combining acute and postacute phases of stroke care and making allowances for case mix as permitted by the quality of the data collected. Those studies looked only at broad differences in practice, generally in the acute phase of care.

A comparison of the UK National Health Service (NHS) and the United States (using data from Kaiser Permanente in California, Medicare California, and U.S. Medicare as a whole) was made with stroke care as 1 key diagnosis.[3] This suggested that for people aged 65 years and older, admissions rates for stroke were broadly similar (NHS, 823/100,000; Kaiser, 788; Medicare California, 1155; U.S. Medicare, 1183). Mean lengths of stay (LOSs) were markedly different (NHS, 27.1d; Kaiser, 4.3d; Medicare California, 5.8d; U.S. Medicare, 6.5d). However, as pointed out by various commentators,[4] the analysis was significantly flawed: for the UK, postacute (ie, rehabilitation) care was included, whereas for the U.S. data, it was not.

New Zealand (NZ) has a public health system modeled on that of the UK, and the Post-Stroke Rehabilitation Outcomes Project (PSROP) provides an opportunity to compare stroke rehabilitation resource use and outcomes, adjusted for case mix, that was not possible in the analysis of Ham et al.[3] We know of no previous attempt to compare inpatient stroke rehabilitation practice between different countries. Previous comparisons of stroke rehabilitation practice across different hospitals but within the same health system have been at the level of retrospective audit of practice, comparing this with short-term outcomes.[5,6]

The PSROP, which includes 6 U.S. sites and 1 NZ site, allows the opportunity to compare stroke rehabilitation practice between the 2 countries at a high level of detail with prospectively obtained data and standardization of data input and outcomes.

We aimed to identify differences in stroke rehabilitation practice between U.S. rehabilitation facilities and NZ hospitals and determine whether these differences affected outcomes at hospital discharge. The null hypothesis was that despite major differences in resource use between the 2 health systems for stroke rehabilitation, for people with stroke admitted to a rehabilitation facility, outcomes in terms of disability and institutionalization at hospital discharge would be similar once allowance was made for stroke case mix.

Stroke Epidemiology and Services in NZ Versus the United States

With what published information is available, it is possible to say that stroke prevalence is broadly similar between NZ and the United States. For people aged 65 years and older in the United States, stroke prevalence was approximately 45 cases per 1000, and in NZ it was 48 cases per 1000.[7] Both populations have dominant white majorities with minority populations that have a higher prevalence of important stroke risk factors and stroke incidence. There is evidence from NZ that Maori and Pacific people who survive a stroke have worse case-mix adjusted outcomes at 12 months than for European New Zealanders.[8] There is also evidence that a similar relation may hold for ethnic minorities in the United States.[9] In both countries, hospital admissions for stroke have increased and stroke mortality has declined over the last 20 years.

In NZ, specialized stroke units for acute care and/or rehabilitation of stroke are rare,[10] and the Wellington site involved in this study did not provide stroke unit care. Wellington is the capital city of NZ, and the health district provides services for about 250,000 people. There are 2 general hospitals, one of which is a university teaching hospital with tertiary services. About 90% of people with acute stroke in NZ are admitted to hospital, generally to a general medical ward.

Average LOS for an acute stroke admission in Wellington is about 7 days. During this acute stay, patients are assessed by members of a rehabilitation service and managed in 1 of 3 ways: likely to die in hospital (managed for whole admission in general medical ward), needs long-term institutional care and unlikely to benefit from short-term inpatient rehabilitation (discharged to institutional care), and may benefit from short-term inpatient rehabilitation (transferred to inpatient rehabilitation service). In Wellington, about 40% of all acute stroke admissions are transferred for inpatient rehabilitation. Depending on where a patient with stroke lives geographically, he/she is managed in 1 of 2 inpatient rehabilitation units, separated by 20km but managed by the same service along similar lines. Inpatient rehabilitation involves intense multidisciplinary team input, and patients are selected on the basis of their ability to participate in an active program of rehabilitation. However, there is no requirement that an arbitrary amount of clinician input (eg, 3h/d) be delivered.

All the hospital care (acute and rehabilitation) is provided free to patients as part of the NZ public health system. Outpatient rehabilitation is also free and provided for a limited time, generally less than 12 weeks.[11] Institutional care is provided with a cost to patients, although this is means tested, and a full government subsidy is provided for about 50% of all patients. Long-term care institutions provide a very limited amount of rehabilitation clinician input—for example, at most 1 hour of physiotherapy (PT) per week and usually no occupational therapy (OT), speech and language pathology (SLP), or social work input. Medical input is from family doctors. There is no equivalent of the skilled nursing facility (SNF) in NZ. This leads to a situation where patients, initially unable to tolerate intensive rehabilitation, might still be admitted to a rehabilitation facility before any consideration of long-term care as an option. In terms of acute and rehabilitation LOS, intensity of inpatient and outpatient rehabilitation, and general rehabilitation practice, Wellington is representative of what happens to people with stroke in most larger centers in NZ.[10]

In the United States, the trajectory of stroke care is somewhat different. After a brief stay in an acute care hospital, patients with stroke typically will be triaged to 1 of several locations: home, a hospital-based rehabilitation center if they are medically stable and can tolerate at least 3 hours of therapy a day, or an SNF if they have not achieved medical stability and are unable to tolerate a full dose of rehabilitation therapy. Those who are discharged home may receive home-based rehabilitation from a home health agency or may receive rehabilitation therapy at a rehabilitation outpatient center. Finally, some will be discharged to a nursing home if they are severely impaired and believed to be unable to benefit from rehabilitation. The transfer to one of these postacute settings is not always systematic and may depend in part on the preferences of a health plan and the advocacy skills of family members. Overall, the setting for postacute stroke rehabilitation will vary with each patient's needs, health plan, family preferences, and geographic location, because types of postacute facilities vary from one part of the United States to another for reasons related to history, degree of urbanization, and the vagaries of local health care markets. Because most stroke survivors are older, they are eligible for Medicare, which remains the dominant payer of stroke rehabilitation services in the United States.

METHODS

The methodology governing the full PSROP, provided in this supplement by Gassaway et al,[12] provides a detailed description of the larger study's participating facilities, patient selection criteria, data collection instruments including their validity and reliability, and a detailed description of the project's final study group. The methodology is summarized in Maulden et al.[13] The institutional review boards at Boston University and at each participating inpatient rehabilitation facility (IRF) approved the study. NZ participants, along with those from 1 U.S. site, gave written consent for a 6-month telephone follow-up.

Wellington was the only non-U.S. site in the PRSOP, comprising 2 rehabilitation facilities that are geographically separated by 20km but are managed by the same overall service along similar lines. All study documentation was identical for both NZ and U.S. participants, with any uncertainties about labeling of specific activities and interventions by different therapists and nurses resolved by discussion with members of the study committee. The data manager for the NZ site (responsible for data extraction from clinical files) was trained in the United States along with U.S. site data managers and remained in close contact with the project manager throughout the study period.

Analysis

Categoric variables were analyzed using the Fisher exact test or chi-square test, and continuous variables were analyzed by *t* test where assumptions of normality were met.

Table 1: Demographic Characteristics and Prestroke Variables

Demographic Characteristics	NZ (n=130)	U.S. (n=1161)	P
Mean age ± SD (y)	74.1±12.6	66.0±14.6	<.001*
Race (%)			<.001†
White	83.1	58.1	
African American	0.0	25.8	
Hispanic	0.0	7.7	
Maori/Pacific	10.8	0.9	
Asian	5.4	5.9	
American Indian	0.0	0.8	
Uncertain	0.8	1.0	
Men (%)	51.5	51.9	1.00†
Health and functional characteristics			
Prior stroke (%)	28.5	27.9	.920†
Hypertension diagnosis (%)	74.6	78.6	.310†
Diabetes diagnosis (%)	20.1	30.8	.020†
Current smoker (%)	24.6	20.9	.190†
Mean weight ± SD (kg)	71.8±16.3	77.0±18.4	.007*
ADL independent before stroke (%)	85.4	91.0	.002†
Ambulant without assistance or device before stroke (%)	73.1	84.1	.005†
Lived alone before stroke (%)	32.3	20.7	.004†

Abbreviation: SD, standard deviation.
*t test.
†Chi-square test.

RESULTS

There were 130 participants from NZ and 1161 participants from U.S. centers for comparison. The NZ population was significantly older (74.1y vs 66.0y, $P<.001$), less ethnically diverse (83.1% vs 58.1% white, $P<.001$), and more dependent before the stroke (dependent for activities of daily living [ADLs], 14.6% vs 9%, $P=.002$; dependent for ambulation: 26.9% vs 15.9%, $P=.005$) (table 1). Patients with stroke in NZ were also more likely to be living alone before their strokes (32.3% vs 20.7%, $P=.004$). Important stroke risk factors were similar in the 2 populations except for diabetes, which was more common in U.S. participants (27.7% vs 20.1%, $P=.02$) and mean weight, which was higher in U.S. participants (77.0kg vs 71.8kg, $P=.007$).

Measures of stroke severity (table 2) at the time of maximum extent were somewhat similar between the 2 populations, including proportion with hemorrhages, proportion with aphasia, complete hemiplegia, and inability to walk. There was a surprisingly big difference in the diagnosis of depression (NZ, 0.8% vs U.S., 12.5%; $P<.001$) and "any mental health disorder" (NZ, 9.2% vs U.S., 54.9%; $P<.001$) between the 2 groups, which may reflect a combination of different thresholds for the diagnosis of a mental health disorder and/or a different level of likelihood that such a diagnosis is documented.

At the time of admission to the rehabilitation facility, U.S. participants had nonsignificantly lower mean FIM scores (U.S., 61.0 vs NZ, 65.6) and significantly higher (worse) Comprehensive Severity Index (CSI) scores (U.S., 20.7 vs NZ, 15.6; $P<.001$) based on the continuous rather than the discrete 4-point version of the CSI.

Regarding the practice of rehabilitation in the different populations, there was a significantly shorter mean delay from stroke onset to rehabilitation admission for NZ participants (11.5d vs 13.8d, $P=.011$), although this was affected in part by a bimodal distribution for the U.S. participants, where the majority had a short delay (U.S. median delay, 7d vs NZ median delay, 9.5d) but others had a substantial delay (eg, entering the rehabilitation facility after a period in an SNF) (table 3).

There was evidence of more intervention in the rehabilitation stay for U.S. participants for feeding (tube feeding: U.S., 16.9% vs NZ, 7.7%; $P=.005$) and oxygen (U.S., 16.5% vs NZ, 5.4%; $P<.001$). The mean rehabilitation LOS was significantly shorter for U.S. participants (18.6d vs 30.0d, $P<.001$), but during that time, more time was spent with a physiotherapist (U.S. mean, 800min vs NZ mean, 460.1min; $P<.001$) and occupational therapist (U.S. mean, 715.0min vs NZ mean, 208.4min; $P<.001$). U.S. participants were seen by a physiotherapist and occupational therapist on a larger proportion of the days that they spent in the rehabilitation facility (mean PT days/mean days in rehabilitation: U.S., 13.5/18.6d vs NZ, 13.3/30d; mean OT days/mean days in rehabilitation: U.S., 11.7/18.6d vs NZ, 5.8/30d).

Because therapists recorded what they did while working with participants, it is possible to make some comments about the actual components of rehabilitation practice within disciplines in the 2 systems.

NZ physiotherapists spent a greater proportion of their time than their U.S. counterparts (table 4) with participants engaged

Table 2: A Comparison of Variables Describing the Extent and/or Consequences of Stroke

Stroke Variable	NZ (n=130)	U.S. (n=1161)	P
Hemorrhage (%)	20.0	23.3	.44§
Nonambulatory at max extent of stroke (%)	62.8	54.1	.09§
Complete hemiplegia (%)	7.7	12.8	.12§
Aphasia (%)	20.0	21.8	.74§
Depression in acute or rehab admission (%)	0.8	12.5	<.001§
Any mental health disorder (%)	9.2	54.9	<.001§
Mean admission to rehab FIM score ± SD			
Total	65.6±28.6	61.0±20.3	.09†
Motor	43.3±21.1	40.1±14.7	.11†
Cognitive	22.3±10.7	21.0±8.3	.17†
CMGs at rehabilitation admission (%)*			<.001§
Mild (CMG 101–103)	32.5	10.0	
Moderate (CMG 104–107)	20.3	44.8	
Severe (CMG 108–114)	47.2	45.2	
Mean discrete CSI ± SD‡	1.28±0.70	1.45±0.63	.005†
Mean rehab admission continuous CSI ± SD‡	15.6±10.5	20.7±13.7	<.001†
Mean increase in severity during admission (max − admission CSI) ± SD‡	10.4±13.0	10.7±11.7	.80†

Abbreviations: CMG, case-mix group; CSI, Comprehensive Severity Index; rehab, rehabilitation.
*Based on CMGs used by the U.S. Centers for Medicare and Medicaid Services in determining amounts of payment under Medicare's prospective payment system for IRFs.
‡For a fuller description of the CSI, see Gassaway et al.[12] Higher scores indicate worse condition.
†t test.
§Chi-square test.

Table 3: Comparison of Process Variables for Inpatient Stay of NZ and U.S. Participants

Process Variables	NZ (n=130)	U.S. (n=1161)	P
Mean onset to rehab admission ± SD (d)	11.5±7.5	13.8±20.8	.011*
Mean acute LOS ± SD	10.4±6.3	8.6±8.4	.004*
Mean rehab LOS ± SD	30.0±19.6	18.6±10.6	<.001*
Mean PT days in rehab ± SD	13.3±11.4	13.5±8.1	.800*
Mean PT minutes in rehab ± SD	460.1±543	800±548	<.001*
Mean OT days in rehab ± SD	5.8±5.2	11.7±7.6	<.001*
Mean OT minutes in rehab ± SD	208.4±265	715.0±537	<.001*
Acute stay tube feed (%)	6.9	21.7	<.001†
Rehab stay tube feeding (any) (%)	7.7	16.9	.005†
Oxygen during rehab stay (%)	5.4	16.5	<.001†

*t test.
†Chi-square test.

in assessment activities and lower-level mobility activities (bed mobility, sitting balance, sit to stand), whereas U.S. therapists spent a greater proportion of their time in higher-level mobility activities (transfers, pregait, gait, advanced gait).

NZ occupational therapists spent a large proportion (NZ, 49.4% vs U.S., 10.7%; $P<.001$) of their time in assessments both in the facility and home. In NZ, a home visit before discharge is virtually routine and usually is conducted by the occupational therapists. Occupational therapists are also responsible for much of the cognitive testing, because psychologists are rarely available or used. On the other hand, U.S. occupational therapists spent a considerable portion of time with participants working with the upper limb, usually the domain of the physiotherapists in NZ.

NZ speech-language therapists spent most of their time with participants involved in assessment of or activities around swallowing (NZ, 50.7% vs U.S., 19.3, $P<.05$), whereas U.S. speech-language therapists spent most of their time in activities around expression, comprehension, and cognitive activities.

Overall, NZ therapists spent more time in assessment and nonfunctional activities than their U.S. counterparts. Nonfunctional activities are activities not directly related to the functional enhancement of a patient or time spent on a patient's behalf but not in direct contact with the patient (eg, time selecting and ordering a wheelchair or splint).

Outcomes at hospital discharge were better for U.S. than NZ participants (table 5). For U.S. participants, fewer participants were discharged to institutional care (U.S., 13.2% vs NZ, 21.5%; $P=.006$), there was a bigger increase in FIM score during admission (U.S., 26.2 vs NZ, 20.6; $P<.001$), and the change in CSI score was greater (U.S., 10.2 vs NZ, 5.6; $P<.001$). It is possible that the criteria for admission to institutional care in the 2 countries may be different. However, it is possible to say that levels of disability at rehabilitation discharge were very similar, with mean FIM scores within 2 points of each other (U.S., 87.2 vs NZ, 85.6; $P=.57$).

DISCUSSION

Our results show that significant differences exist for stroke rehabilitation practice and outcomes for participants in NZ and U.S. rehabilitation facilities. NZ participants tended to be older, frailer, and more likely to live alone before stroke, but U.S. participants scored somewhat worse on measures of disability and comorbidity at the beginning of stroke rehabilitation. U.S. participants stayed a much shorter time in the rehabilitation facility but had much higher input from PT and OT in that time, both in terms of the proportion of days on which they were seen and the total number of minutes of time.

U.S. participants had better outcomes, with more rapid change in disability scores and a lower chance of discharge to

Table 4: Comparison of the Components of Rehabilitation Practice: PT, OT, and SLP

Activity	Percent of Total Time Spent in Each Class of Activity: NZ	U.S.	P
PT			
Assessment	15.7	9.6	.001*
Movement activities before transfers	32.4	24.3	<.001*
Movement activities, transfers, and walking	38.7	54.0	<.001*
Nonfunctional time	23.3	21.5	.400*
OT			
Assessments	49.4	10.7	<.001*
ADLs	30.5	31.0	.870*
Mobility activities including transfers and wheelchair	13.0	20.1	.016*
Working with upper limb	0.9	24.6	<.001*
Home management, leisure, and community integration	9.5	12.9	.147*
Nonfunctional activities	18.8	10.6	.014*
SLP			
Assessment	26.9	19.3	.100*
Swallowing	50.7	19.3	<.050*
Voice and expression activities	30.8	31.2	.940*
Comprehension activities	6.4	14.4	<.001*
Memory, problem solving, and other cognitive activities	2.4	33.3	<.001*
Nonfunctional activities	8.5	1.1	<.050*

*t test.

Table 5: Comparison of Outcomes for NZ and U.S. Participants

Outcome Variables	NZ (n=130)	U.S. (n=1161)	P
Discharge destination, n (%)			.006*
Home	92 (70.8)	906 (78.0)	
Community assisted living	3 (2.3)	34 (2.9)	
Institutional	28 (21.5)	153 (13.2)	
Hospital	1 (0.8)	47 (4.1)	
Other acute rehab	3 (2.3)	15 (1.3)	
Died	3 (2.3)	6 (0.5)	
Mean discharge FIM score ± SD	85.6±30.7	87.2±22.5	.570†
Mean increase in FIM score ± SD	20.6±15.2	26.2±14.0	<.001†
Mean net medical improvement (admission − discharge CSI) ± SD‡	5.6±14.5	10.2±10.7	<.001†
Mean rehab discharge CSI continuous scores ± SD‡	10.0±16.0	10.5±12.6	.600†

*Chi-square test.
†*t* test.
‡For a fuller description of the CSI, see Gassaway et al.[12] Higher scores indicate worse condition.

institutional care. These differences occurred despite the increased severity of U.S. participants' disabilities at the time of their rehabilitation admissions.

The components of rehabilitation practice for different types of therapists were surprisingly different between NZ and U.S. facilities. U.S. therapists of all types spent a smaller proportion of their time in assessment and nonfunctional activities and proportionately more time in active management of participants. This was particularly so for occupational therapists. U.S. occupational therapists spent almost a quarter of their time involved in activities with the upper limb, an activity rarely performed by NZ occupational therapists and more often performed by NZ physiotherapists, as noted earlier. Speech-language therapists in NZ spent more of their time involved in swallowing activities than the more traditional speech and language activities, whereas U.S. speech-language therapists provided significant input into cognitive activities.

There are some major questions that might affect the interpretation of these results. First, how representative of NZ and U.S. practice are the facilities studied? Certainly, the NZ facility falls somewhere in the middle of NZ rehabilitation facilities for efficiency (rehabilitation LOS), and the staffing is broadly similar with other units in the country. The 6 U.S. facilities in the PSROP are a geographically diverse group of IRFs, and based on comparisons with a more nationally representative group of IRFs,[14] these 6 facilities serve a somewhat nationally representative sample of stroke rehabilitation patients served in IRFs.

Second, how much difference does the age disparity between the U.S. and NZ study groups make on outcome, particularly institutionalization? One could argue that the older population studied in NZ was at higher risk of poststroke rehabilitation institutionalization. For study participants as a whole, increasing age was only very weakly associated with institutionalization. In an earlier NZ study, age was not a significant independent variable in rate of change of disability in hospital for people with stroke,[14] suggesting that the age difference cannot be the sole explanation for the differences in practice patterns and outcomes reported here.

The cause of the age disparity needs to be considered, because this may suggest important unmeasured covariates in outcome. With the availability of additional postacute rehabilitation venues such as SNFs in the United States, it is possible that older patients with stroke in the United States are more likely to be managed in an alternative postacute setting than those in NZ. One consequence of this is that in NZ, a significant proportion of elderly people with stroke will be "given a go" in a rehabilitation facility, with a fairly high expectation of the need for eventual institutional care rather than for discharge direct from an acute hospital to the institutional setting. NZ lacks SNFs either as an alternative to an IRF or as an intermediate step on the way to an IRF. It could be argued that such facilities might inadvertently help improve the effectiveness and efficiency of rehabilitation facilities by enabling IRFs to work with patients who are more likely to succeed with IRF-level care. Thus, in the U.S., hospital-based rehabilitation facilities may be less likely to admit patients with any risk of not being discharged to home. This would have the effect of reducing the age of the population admitted to an IRF and providing a small advantage in favor of discharge home compared with NZ participants. Published U.S. data from 1999 show a mean age for patients with stroke admitted to IRFs of 70 years,[15] whereas that for patients with stroke admitted to subacute rehabilitation facilities (mainly SNFs) was 76 years,[16] suggesting some sort of selection process related to age. Nevertheless, age aside, the severity indicators in this study, which included various comorbid conditions, favored the NZ participants.

The higher proportion of NZ patients living alone before their strokes may have influenced more to be discharged to institutions. The NZ mean discharge FIM score of 85.6 indicates that a large proportion of those discharged required continued assistance. The relatively similar discharge FIM and CSI scores at discharge for the 2 patient groups would suggest that the differences were not due to clinical factors.

There is an increasing body of evidence that increasing the intensity of stroke rehabilitation improves outcomes,[17,18] and this study supports that notion. Although the case mix of these compared populations had differences, an analysis of these differences tends to support the conclusion that increased therapy intensity results in more rapid functional improvement in patients early after stroke. The difference in the rate of change of FIM scores between the groups was substantial. As discussed earlier, previous studies found that age had little effect on these rates of change. It seems possible that medical severity could delay functional recovery, yet it was greater in the U.S. population, which showed the fastest and greatest improvement. The discharge FIM scores of the 2 groups were not significantly different, so the prestroke differences in function do not seem to have had substantive effects. The closeness of the admission FIM scores suggests that the ceiling effects of the FIM had little influence. Living alone before admission should not influence functional capacity. Depression and mental health disorders would be more likely to slow rather than increase improvement rates. Although further studies on more closely matched populations may be needed to ultimately clarify the impact of more intense therapy, the evidence strongly suggests that more intensity can result in greater and more rapid gains in appropriately selected patients with stroke.

CONCLUSIONS

This study shows that it is not only the total hours of therapy that are important but what happens during the therapy session. Rehabilitation services that manage people with stroke should consider the level of intensity of therapy input and concentrate on active therapy. For NZ services, an overemphasis on assessment may contribute to delays in initiating active therapy, leading in turn to longer-than-necessary stays in a hospital.

Given the therapy intensity for U.S. patients observed in this study, there may be ample opportunity to increase therapist input for NZ patients on more days during a rehabilitation stay. The NZ public health system has tended to focus too much on overall costs without examining the components of those costs that make a difference. Practices to promote efficiency, or better outcomes if they involve new spending (eg, such as more staff or staff working on 6 days rather than 5), have been difficult to implement. The results reported here provide some focus for a change in mindset that should benefit patients with stroke. It should be noted, however, that the costs of inpatient rehabilitation in the 2 countries are massively different—for NZ, the per-day cost is around US$320, whereas U.S. rehabilitation facilities charge around US$1050/d. Even with a much shorter LOS, the mean total cost of a rehabilitation stay in a U.S. facility is almost double that in NZ. Depending on one's perspective (eg, patient, clinician, funder), the difference in outcomes reported here may or may not represent good value.

The other lesson from this study is that there is much to be learned from rehabilitation practitioners in different countries and different parts of the same country if robust study methods and analysis can be adopted. We note with interest a European study hosted at the Free University of Brussels with design elements similar to this study. That study, known as the Collaborative Evaluation of Rehabilitation in Stroke Across Europe, is investigating stroke rehabilitation practice in 4 European countries. Incorporating the best elements from many service delivery models may provide a rapid way to achieve better outcomes for people with stroke.

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COMMENTARY

The Post-Stroke Rehabilitation Outcomes Project

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The Post-Stroke Rehabilitation Outcomes Project (PSROP) examined a large sample of patients from multiple facilities receiving inpatient stroke rehabilitation services. This commentary describes strengths and potential limitations of the investigation including selection bias, observation bias, confounds, and interpretation. The PSROP is an important study that will advance our understanding of effective treatment for persons with stroke.

Key Words: Rehabilitation; Stroke.

THE POST-STROKE REHABILITATION Outcomes Project (PSROP) is an important study on a major public health problem.[1] The World Health Organization projects that stroke will become a leading cause of mortality worldwide in this century.[2,3] More than 50% of those 65 years and older who survive a stroke report hemiparesis at 6 month follow-up. Thirty percent of persons (≥65y) are unable to walk without assistance and 26% are dependent in at least 1 basic activity of daily living 6 months poststroke.[1] The social and economic impact of stroke are well described by DeJong et al[4] and demonstrate the need for the PSROP.

During the past 2 decades, dramatic improvements have been made in the treatment of stroke and convincing scientific evidence now exists that stroke rehabilitation programs are effective. The evidence on overall efficacy is summarized in *Recovery After Stroke*[5] and other recent publications.[6,7] What we do not know is which patients are the best candidates for the complex array of rehabilitation methods and techniques currently available.[6] DeJong refers to this problem as the "black box" of stroke rehabilitation and notes: "the interaction between each stroke survivor, his/her comorbidities, personal behaviors, and coping abilities and all of these health care providers and family members is complex and highly specific—with each and all factors having a possible impact on the patient's outcome."[4(p2)] The PSROP investigators should be congratulated on their efforts to examine systematically the black box of stroke rehabilitation, including the complex interactions among patient characteristics, treatment approaches, and rehabilitation outcomes.

The method they have selected, clinical practice improvement (CPI), is an innovative and powerful approach designed to examine complicated research questions in a real-world setting. The findings are presented as a series of observational "cohort" investigations that represent a descriptive epidemiology of stroke rehabilitation. The strengths of the approach are the relevance to real-world clinical practice, the focus on the care management process, the inclusion of a wide range of patients, the collection of a large amount of treatment and outcome data, and the active participation of front-line clinicians in the planning and implementation of the study. These factors all add to the ecologic validity of the PSROP.

Regarding internal validity, the authors discuss several recent investigations[8,9] comparing outcomes for randomized controlled trials (RCTs) and observational studies. These studies suggest that well-described cohort and case-control investigations produce results that are similar to RCTs. These investigations, however, examined cohort and case-control studies that involved comparison or control groups, masked recording of outcomes, and included dependent measures with established reliability and validity. As an observational study, the PSROP does not include many of these design features. The PSROP results must be carefully examined in relation to the potential limitations associated with observational investigations. This is particularly true in view of the absence of a comprehensive description of the limitations of the PSROP. In discussing the combined series of analyses included in the PSROP, the only limitation identified in the article by DeJong[4] is the failure to collect follow-up data across all the participating sites.

The remainder of this commentary describes potential limitations associated with observational studies and briefly discusses how these relate to the PSROP. My comments are directed at areas of potential concern relevant to prospective cohort studies. These concerns are selection bias, observational bias, confounds, and interpretation.

SELECTION BIAS

Selection bias occurs when there is a preferential inclusion of subjects with certain treatment outcomes.[10] In cohort studies, this usually occurs when information is less likely to be collected or analyzed from subjects who have better (or worse) outcomes. In the PSROP, the potential for selection bias is subtle because 2 cohorts (eg, treatment vs control) were not followed. In several of the analyses reported in the PSROP, however, 1 subgroup of patients is compared with another subgroup. For example, patients who received early therapy were compared with patients receiving later therapy, or patients receiving new antidepressant drugs were compared with patients administered older medications. In some cases, patients in various case-mix groups were selected for analysis and others were excluded. Patients in these subgroups may have differed in ways unknown to the investigators and not adjusted for in the statistical analyses (see Confounds below).

OBSERVATION BIAS

Observation or information bias is associated with measurement error that can be introduced in various ways.[10] One strength of the PSROP is the involvement of front-line clinicians in the development of the data collection instrument and actual data gathering and recording. The participation of ther-

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apists ensures the outcomes will be clinically relevant, but also introduces a potential bias. The therapists collecting and recording data are aware of the study, its purpose, and its goals, and this may (unconsciously) affect how they treat patients and/or record data. This is frequently referred to as the Hawthorne or experimenter effect, and there is a large literature on how it can impact study outcomes.[11,12] Observation bias is known to be a potential problem in stroke rehabilitation cohort-type investigations. A previous meta-analysis[13] of stroke rehabilitation studies found an interaction between design quality and study outcome that was moderated by whether or not the outcome was blindly recorded. There was no difference in outcomes between RCTs and nonrandomized studies when both sets of trials used blind recoding of the primary outcome. There were significant differences, however, when blind recording was not used, with the nonrandomized cohort studies reporting larger effect sizes and more statistically significant results.

Another area of observation bias that deserves mention relates to recording large amounts of data from medical records. No information on the accuracy or consistency of abstracting this information from the medical or other health care records is provided.

CONFOUNDS

Confounding occurs when 2 factors are associated with each other, and the effect of one is confused with or distorted by the effect of the other. Confounding variables differ from effect modifiers or moderator variables, but both influence outcomes.[10] Confounding variables are usually controlled by manipulation of the study design or statistical methods. In the PSROP, confounding is controlled statistically. Statistical control requires that the confounding variables are known and measured. In clinical cohort studies, there are usually not enough subjects included or variables measured to statistically control for many confounding factors. Strengths of the CPI approach include the recruitment of a large and heterogeneous sample of patients and measurement of a substantial number of potential confounding variables. The Comprehensive Severity Index (CSI) was used to control for differences in patient severity of illness, including comorbidities. The CSI is described as an age- and disease-specific measure of physiologic and psychologic complexity comprised of over 2000 signs, symptoms, and physical findings.[14] Little operational detail is provided about the CSI and its use in stroke rehabilitation. The cited references focus on acute care hospitalization with an emphasis on pediatrics. We do not know what variables went into the CSI, how the variables were weighted, or how missing data were handled. In the results from the summary article on early and more aggressive therapy,[15] the CSI did not enter into several of the regression equations, suggesting that admission FIM and other severity-related variables shared substantial variance with CSI scores. The usefulness of the CSI relative to other potential severity adjustors such as function-related groups, and admission FIM instrument motor and/or cognitive ratings requires further investigation, particularly in view of the investigator and/or respondent burden for collecting the substantial amount of information required by the CSI.

In some analyses, general statements are made that variables were controlled for in the regression equations, but the method of control is not always clear. We do not know the ratio of variables to subjects, if interactions were tested, or if all assumptions were met for complex regression models. While the overall sample is relatively large for a clinical study, many of the regression analyses appear to include smaller numbers of subjects. More than 120 variables are listed in appendix 1, yet some of the regression models described in table 8 include fewer than 120 subjects.[15]

INTERPRETATION

A final issue involves the level of inference that can be drawn from the data collected and analyzed in the PSROP. The article by Horn et al[15] includes an excellent discussion comparing and contrasting RCTs and observational studies. I agree with the need for a broader approach to research design and the inclusion of methods other than RCTs in the generation of evidence-based knowledge for rehabilitation. While I am sympathetic to the idea that there are multiple approaches to establishing valid scientific information, we must recognize the limitations on inferences that can be drawn from a single observational study. Observational investigations, including the PSROP, provide data on associations among variables. These associations are important and can lead to improvements in practice if they are replicated and validated. Data from a single observational study do not allow the investigators to make causal inferences.[10] There are many statements in the PSROP articles that imply causality. This confusion about association versus causation is reflected in the statement of the PSROP's principle research question presented by DeJong et al: "[W]hat *impact* does each stroke rehabilitation activity or intervention, both individually and collectively, have on patient outcomes on discharge controlling for patient differences including medical and functional status on admission? (emphasis added)."[4(p3)] Based on the PSROP design, this question would be better phrased as, "What is the association between each stroke rehabilitation. . . ." There are numerous instances where "impact," "affect," "influence," and "responsible for" are used to describe the connection between variables and outcomes. There are also many examples throughout the articles where the terms *association* and *relationship* are used appropriately. Cumulatively, however, the inconsistent use of terms implying both causation and association contribute to the authors' proposing recommendations for changes in practice that, in my opinion, are premature based on associational data from 1 study (sample).

The issues of interpretation and implications for clinical practice are directly related to establishing a research foundation for evidenced-based rehabilitation. The evidence provided by the PSROP investigation would be considered level 3 or 4 using the Center for Evidence-Based Medicine criteria.[16] The importance of using appropriate levels of evidence to guide clinical practice has recently been illustrated in the radical change in practice recommendations on the use of hormone replacement therapy in postmenopausal women. Practice guidelines changed dramatically when large randomized trials did not support the findings of earlier observational studies.[17]

CONCLUSIONS

The limitations outlined above are essential to consider in evaluating the PSROP findings, but they should not detract from the importance of this research effort. The PSROP is an impressive and valuable addition to the scientific literature in stroke rehabilitation. The study provides crucial new findings and expands our understanding of the rehabilitation process applied to persons with stroke. We are all keenly aware that any investigation, particularly one as large and complex as the PSROP, will have limitations. These limitations should be recognized in order to help interpret the findings and better plan future research. The PSROP investigators have opened the lid of stroke rehabilitation's black box. Thanks to their efforts, we

have the opportunity to peer into the black box and begin the exciting challenge of exploring its contents.

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COMMENTARY

The Post-Stroke Rehabilitation Outcomes Project

Alan M. Jette, PT, PhD

ABSTRACT. Jette AM. The Post-Stroke Rehabilitation Outcomes Project. Arch Phys Med Rehabil 2005;86(12 Suppl 2): S124-5.

The Post-Stroke Rehabilitation Outcomes Project (PSROP) provides an important example of the value of observational study designs in rehabilitation. The strength of the PSROP lies in the extensive, in-depth data collected on the specific rehabilitation interventions provided to patients and their relationship to short-term outcomes as well as the wide generalizability of the study's findings. Although providing valuable insights, one has to be extremely cautious in drawing direct practice recommendations from the PSROP given several internal validity threats inherent in the PSROP design.

Key Words: Rehabilitation; Stroke.

I CONGRATULATE DR. HORN and colleagues on the successful completion of their ambitious multicenter, multinational Post-Stroke Rehabilitation Outcomes Project (PSROP) and in organizing their major findings in this supplement of *Archives.*

In the interest of full disclosure, readers should know that the PSROP, an in-depth observational investigation of stroke rehabilitation practice variation and its relationship to short-term outcomes, was conceived and partially funded under the auspices the Rehabilitation Research and Training Center on Medical Rehabilitation Outcomes that I directed. I had the distinct privilege of collaborating with Horn and colleagues in the overall planning for the PSROP.

In this supplement, the authors address a critically important question faced not only in stroke rehabilitation but also in most areas of rehabilitation: What is the measurable impact of rehabilitation activities or interventions, both individually and collectively, on patient outcomes on discharge from inpatient rehabilitation care? There is great pressure on rehabilitation providers to demonstrate the effectiveness of what they do. Concerns over the rapidly escalating costs of postacute care have focused unprecedented attention on the concern that the rehabilitation services delivered to our patients may achieve at best only marginal improvements in health at a considerable cost. The pressure to control costs has prompted a call for better data on the outcome or effectiveness of rehabilitation care. The PSROP provides the rehabilitation field with an important additional method to respond to such calls.

The classic research approach to establishing the effectiveness of a particular health care service is to launch a carefully designed randomized controlled trial to evaluate the value of a particular service for a carefully defined group of patients. While this strategy can and is being used successfully in rehabilitation in an increasing number of areas, extending such an approach to all aspects of rehabilitation services would be prohibitively expensive, be difficult to mount, and take decades to achieve. An alternative approach, long employed in other areas of health care, is the use of observational designs. The basic analytic challenge in an observational design, such as the PSROP, is to assess the effectiveness of rehabilitation care by dissecting out the effects of treatment from the competitive effects of other factors, most notably, a patient's baseline status, relevant patient demographic and clinical factors, environmental factors, and competing treatment effects. The strength of such a design lies in the wide generalizability of the finding; the concern usually rests with how well it protects against major threats to the internal validity of the study's results.

The PSROP used a particular observational approach—clinical practice improvement (CPI)—developed by Horn. Although similar to most observational methodologies in its inclusion of broadly defined groups of patients and in its use of multivariate statistical analyses to dissect out the effects of treatment from other pertinent factors, in my view, this CPI methodology differs from other observational methodologies in the active collaboration of front-line clinicians in the planning as well as in the development of data collection instruments, in actual collection of the data, and in analysis and reporting of the findings. I believe the success of the PSROP depends heavily on the active involvement of front-line clinicians in each of the participating sites who contributed to the planning of the study design, development of the taxonomy used to characterize rehabilitation activities employed in the study, in collection of the data documenting stroke rehabilitation interventions, and in data analysis and interpretation.

The level of involvement of site clinicians was quite remarkable and a tribute to the skill of the research team as well as to the commitment of the participating clinicians. Aware of the limitations of using the medical record as the source of data to document the care provided to stroke patients, and the unavailability of existing standardized intervention documentation forms, the study's clinicians (ie, physicians, nurses, psychologists, social workers, and physical, occupational, recreational, and speech therapists) each created a standardized form to include the level of intervention specificity they believed was necessary to capture a complete and accurate picture of what was done by that discipline related to the rehabilitation care of each patient enrolled in the study. Each discipline developed its own content in collaboration with the PSROP study investigators and standardized the frequency with which the form would be completed. Protocols called for the intervention forms to be completed for each therapy session and nursing day for each study patient who was enrolled. The sheer volume of intervention data collected with these protocols is impressive. For the 1291 poststroke rehabilitation patients enrolled in the PSROP, a total of 141,511 forms were completed across all disciplines by clinicians who were involved in the PSROP. This is a remarkable achievement and provides the field with rehabilitation documentation protocols that are now available for fu-

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ture investigations. The key to their success with these forms, I believe, was the PSROP team's ability to give the participating clinicians ownership in the development of the data collection processes.

The PSROP investigators carefully attempted to standardize not only the documentation forms themselves but also their application. They trained participating clinicians in the use of the intervention documentation forms via discipline-specific train-the-trainer teleconferences attended by the lead clinicians from each facility. These lead clinicians trained others from their site. This training was supplemented with a training manual, detailed instructions, case studies, and definitions for all terms used on the forms. Unfortunately, data were not collected to verify the success of this impressive effort. We do not know if what clinicians recorded on the forms accurately represents what was actually done, whether the data recorded were complete, or the degree of consistency achieved across participating clinicians, or over time. These tasks were beyond the scope of what could be accomplished with the available funding. The field will have to await data from future studies to answer these important questions.

A second area that I would like to comment on is the conclusions that one draws from observational studies such as the PSROP. In the article by Horn et al,[1] the investigators report on the observed associations between over 100 patient characteristics, therapies, neurotropic medications, nutritional support, and the timing of rehabilitation with motor and cognitive functional outcomes and discharge destination. Horn focuses on 2 key findings that challenge conventional wisdom in rehabilitation practice. The first is that the more quickly a stroke patient starts inpatient rehabilitation after their stroke, the better the outcomes. Moreover, Horn reports that earlier gait activities, particularly in the first block of physical therapy (PT), have a significant effect on outcome regardless of how much additional therapy a patient receives.

Horn suggests that the findings argue for a more "aggressive approach" to PT and concludes that the results suggest that health care providers might need to shorten the duration from onset of stroke to onset of rehabilitation; to move patients as quickly as possible to higher-level, more difficult therapy activities.

I believe one has to be extremely cautious in drawing direct practice recommendations from the PSROP findings given several internal validity threats inherent in the PSROP design. With over 100 independent variables tested in several different multivariate models without specific a priori hypotheses, the risk of committing a type I error was considerable. Sample size limitations precluded the splitting of the sample into 2 random subsamples so that initial models could be built on 1 sample and replicated in a second subsample drawn from the same study sample. Second, the PSROP relied on the medical record as the primary source of data for many of the major clinical, demographic, and some treatment variables that were critical to controlling for potential confounding in their multivariate models. The lack of evidence of the completeness, reliability, and validity of these medical record data along with the legendary concerns about reporting and misclassification errors inherent in the medical record, gives me concern that some important potential confounding influences may have been inadequately identified and measured, and therefore not adequately controlled for in their analyses. A major concern is the probability that patients who received the early and more aggressive therapy were different from those who did not in ways that were also related to improved functional outcome. For example, provision of more aggressive therapy might have been related to the patient's motivation or level of perceived self-efficacy that might also be related to patient outcome. These psychologic factors were not measured in the study or available in the medical record and therefore could be an alternative explanation for the association between timing and type of therapy and the functional outcome. These internal validity concerns are common in observational designs such as the PSROP and argue for considerable caution in the extent to which action recommendations can be drawn from the findings of any 1 study.

I believe the findings of the PSROP reported in this supplement are extremely valuable. For me, the major implication of Horn's results is that their compelling finding related to the timing and nature of the PT interventions and more positive outcomes demand further testing and investigation. The associations need to be examined in different settings, with different samples of clinicians, and with different patients to enhance their internal validity. Until the major PSROS findings on the association of early and more aggressive therapy interventions with stroke patients can be replicated, however, I believe it is premature to advocate changes in practice patterns or policy changes.

The PSROP provides an important example of the value of observational study designs in rehabilitation, and I applaud the investigators for their important accomplishment, one that I hope is replicated by others. The PSROP provides us with an important additional method to respond to calls for the rehabilitation field to demonstrate the effectiveness of the services it provides.

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